

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

*Lonapegsomatropin (Skytrofa®)*

Ascendis Pharma Endocrinology GmbH

**Separater Anhang 4-G**

*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 ITT Population.....	3
Table 1.16 Change from Baseline in Height SDS at Week 52: ANCOVA Analysis, subgroup analysis ITT Population.....	9
Table 1.22 Summary of Adverse Events, subgroup analysis by age Safety Population.....	15
Table 1.23 Summary of Adverse Events, subgroup analysis by gender Safety Population.....	17
Table 1.24 Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata Safety Population.....	19
Table 1.25 Summary of Adverse Events, subgroup analysis by etiology and extend of GHD Safety Population.....	21
Table 1.26 Summary of Adverse Events, subgroup analysis by region Safety Population.....	24
Table 1.27 Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline Safety Population.....	27
Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population.....	29
Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population.....	142
Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population.....	254
Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population.....	370
Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population.....	527
Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population.....	684
Table 1.43 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age Safety Population....	798
Table 1.44 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender Safety Population	800
Table 1.45 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 Safety Population.....	804
Table 1.46 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 Safety Population.....	808
Table 1.47 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by region Safety Population.	814
Table 1.48 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 at baseline Safety Population.....	820
Table 1.50 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study Summary of Subjects with Injection Related Events, subgroup analysis by age Safety Population.....	824

Table 1.51 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study Summary of Subjects with Injection Related Events, subgroup analysis by gender Safety Population.....	828
Table 1.52 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 Safety Population.....	832
Table 1.53 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 Safety Population.....	836
Table 1.54 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study Summary of Subjects with Injection Related Events, subgroup analysis by region Safety Population.....	842
Table 1.55 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 at baseline Safety Population.....	848

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

Age	Baseline		Week 52			TransCon hGH vs. Genotropin				
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in		Hedges'g	Interaction	
Sub Group Treatment						LS Mean <sup>c</sup> [95 %-CI]	p-value	[95 %-CI]	p-value	
<b>AGE &lt; 6 Years</b>										
TransCon hGH	25/24	4.91 (2.410)	25/25	11.87 (2.067)	12.41 (0.486)	1.58 [0.254, 2.915]	0.0211	0.67 [-0.003,1.340]	0.0838	
Genotropin	14/13	4.46 (1.427)	14/14	10.48 (2.114)	10.82 (0.630)					
<b>AGE &gt;= 6 Years</b>										
TransCon hGH	80/70	3.59 (1.799)	80/80	10.58 (2.272)	10.72 (0.262)	0.51 [-0.227, 1.242]	0.1756	0.18 [-0.191,0.558]		
Genotropin	42/41	3.76 (1.710)	42/42	10.16 (2.450)	10.21 (0.330)					

Missing data are imputed with multiple imputation method. For each imputed data set, an ANCOVA model with by visit annualized height velocity as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS - average SDS of parental height as covariates are fitted. The LS means, confidence intervals, and p-values presented in the table are the overall estimates combined from all the 100 models. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. The interaction p-value of Etiology and extend of GHD and Region are the median value across the 100 models is presented in the table.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ahv-ancova-mi-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:10 Page 1 of 6

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

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Genotropin				
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value	
<b>Male</b>										
TransCon hGH	86/78	4.04 (2.088)	86/86	10.67 (2.167)	10.74 (0.213)	0.81 [0.094, 1.520]	0.0266	0.27 [-0.087,0.633]	0.9800	
Genotropin	46/44	4.10 (1.512)	46/46	10.07 (2.302)	9.93 (0.293)					
<b>Female</b>										
TransCon hGH	19/16	3.42 (1.769)	19/19	11.89 (2.575)	11.79 (0.461)	0.59 [-1.074, 2.260]	0.4697	0.34 [-0.434,1.107]		
Genotropin	10/10	3.17 (2.134)	10/10	11.02 (2.567)	11.20 (0.645)					

Missing data are imputed with multiple imputation method. For each imputed data set, an ANCOVA model with by visit annualized height velocity as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS - average SDS of parental height as covariates are fitted. The LS means, confidence intervals, and p-values presented in the table are the overall estimates combined from all the 100 models. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. The interaction p-value of Etiology and extend of GHD and Region are the median value across the 100 models is presented in the table.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ahv-ancova-mi-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:10 Page 2 of 6

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

Baseline GH-stimulation strata											
Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Genotropin					
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]		p-value	Hedges'g [95 %-CI]	Interaction p-value	
<b>&lt;=5 ng/mL</b>											
TransCon hGH	37/34	3.80 (1.940)	37/37	11.45 (2.739)	11.98 (0.445)	0.74 [-0.584, 2.070]		0.2723	0.23 [-0.309,0.765]		0.9760
Genotropin	21/20	4.01 (1.332)	21/21	10.82 (2.819)	11.23 (0.591)						
<b>&gt;5 ng/mL</b>											
TransCon hGH	68/60	4.00 (2.110)	68/68	10.58 (1.945)	10.56 (0.263)	0.84 [0.146, 1.524]		0.0175	0.36 [-0.054,0.767]		
Genotropin	35/34	3.88 (1.846)	35/35	9.88 (1.991)	9.72 (0.325)						

Missing data are imputed with multiple imputation method. For each imputed data set, an ANCOVA model with by visit annualized height velocity as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS - average SDS of parental height as covariates are fitted. The LS means, confidence intervals, and p-values presented in the table are the overall estimates combined from all the 100 models. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. The interaction p-value of Etiology and extend of GHD and Region are the median value across the 100 models is presented in the table.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ahv-ancova-mi-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:10 Page 3 of 6

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

Etiology and extend of GHD

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Genotropin			
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value
<b>Isolated Idiopathic</b>									
TransCon hGH	68/60	4.10 (2.213)	68/68	10.28 (1.841)	10.40 (0.292)	0.67 [-0.048, 1.390]	0.0674	0.31 [-0.092,0.713]	0.9268
Genotropin	37/36	4.12 (1.622)	37/37	9.68 (2.146)	9.73 (0.343)				
<b>Isolated Organic</b>									
TransCon hGH	19/17	4.43 (1.622)	19/19	11.57 (1.975)	11.57 (0.442)	1.09 [-0.335, 2.513]	0.1269	0.22 [-0.575,1.016]	
Genotropin	9/9	3.23 (1.911)	9/9	11.13 (1.978)	10.48 (0.529)				
<b>Multiple Pituitary Hormone Deficiencies</b>									
TransCon hGH	18/17	2.83 (1.368)	18/18	12.47 (3.122)	12.68 (0.691)	0.48 [-2.046, 3.004]	0.6977	0.32 [-0.458,1.098]	
Genotropin	10/9	3.86 (1.556)	10/10	11.50 (2.856)	12.20 (1.035)				

Missing data are imputed with multiple imputation method. For each imputed data set, an ANCOVA model with by visit annualized height velocity as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS - average SDS of parental height as covariates are fitted. The LS means, confidence intervals, and p-values presented in the table are the overall estimates combined from all the 100 models. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. The interaction p-value of Etiology and extend of GHD and Region are the median value across the 100 models is presented in the table.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ahv-ancova-mi-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:10 Page 4 of 6

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

Region	Baseline		Week 52			TransCon hGH vs. Genotropin				
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value	
North America										
TransCon hGH	27/24	4.32 (2.078)	27/27	9.66 (1.705)	9.50 (0.564)	0.24 [-1.104, 1.583]	0.7268	0.19 [-0.446,0.819]	0.7557	
Genotropin	15/15	4.40 (1.185)	15/15	9.28 (2.597)	9.26 (0.541)					
Europe										
TransCon hGH	66/60	3.72 (2.065)	66/66	11.45 (2.403)	11.77 (0.292)	0.91 [0.052, 1.775]	0.0377	0.30 [-0.124,0.734]		
Genotropin	31/29	3.60 (1.841)	31/31	10.73 (2.255)	10.86 (0.394)					
Rest of the World										
TransCon hGH	12/10	4.26 (1.809)	12/12	10.56 (1.588)	10.86 (0.648)	0.83 [-1.165, 2.833]	0.3894	0.24 [-0.604,1.081]		
Genotropin	10/10	4.16 (1.659)	10/10	10.13 (2.021)	10.02 (0.908)					

Missing data are imputed with multiple imputation method. For each imputed data set, an ANCOVA model with by visit annualized height velocity as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS - average SDS of parental height as covariates are fitted. The LS means, confidence intervals, and p-values presented in the table are the overall estimates combined from all the 100 models. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. The interaction p-value of Etiology and extend of GHD and Region are the median value across the 100 models is presented in the table.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ahv-ancova-mi-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:10 Page 5 of 6



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

Peak stimulated GH concentration at baseline

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Genotropin			
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value
<b>&lt; 8 ng/mL</b>									
TransCon hGH	76/69	3.81 (2.151)	76/76	11.13 (2.478)	11.45 (0.282)	1.04 [0.243, 1.839]	0.0106	0.34 [-0.043,0.722]	0.3660
Genotropin	41/40	3.81 (1.579)	41/41	10.29 (2.463)	10.41 (0.368)				
<b>&gt;= 8 ng/mL</b>									
TransCon hGH	29/25	4.26 (1.703)	29/29	10.27 (1.531)	10.38 (0.410)	0.29 [-0.780, 1.365]	0.5837	0.10 [-0.524,0.723]	
Genotropin	15/14	4.25 (1.907)	15/15	10.10 (2.108)	10.09 (0.488)				

Missing data are imputed with multiple imputation method. For each imputed data set, an ANCOVA model with by visit annualized height velocity as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS - average SDS of parental height as covariates are fitted. The LS means, confidence intervals, and p-values presented in the table are the overall estimates combined from all the 100 models. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. The interaction p-value of Etiology and extend of GHD and Region are the median value across the 100 models is presented in the table.

Source: ... \biometrics\hgh\ct-301\ad hoc\amnog\_dossier\prog\t-ahv-ancova-mi-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:10 Page 6 of 6

Table 1.16 Change from Baseline in Height SDS at Week 52: ANCOVA Analysis, subgroup analysis  
ITT Population

Age	Baseline		Week 52			TransCon hGH vs. Genotropin			
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value
<b>AGE &lt; 6 Years</b>									
TransCon hGH	25/25	-2.83 (0.694)	25/25	1.30 (0.467)	1.42 (0.096)	0.33 [0.073,0.584]	0.0134	0.61 [-0.061,1.277]	0.1977
Genotropin	14/14	-2.93 (0.793)	14/14	1.04 (0.372)	1.09 (0.123)				
<b>AGE &gt;= 6 Years</b>									
TransCon hGH	80/80	-2.90 (0.892)	80/79	0.94 (0.476)	0.99 (0.042)	0.07 [-0.048,0.194]	0.2345	0.15 [-0.229,0.526]	
Genotropin	42/42	-3.02 (0.944)	42/41	0.87 (0.477)	0.92 (0.054)				

An ANCOVA model with by visit change from baseline in height SDS as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS as covariates is fitted. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. Mean (SD) values are the observed data.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-hgsd-ancova-sub.sas  
Data Extracted: 03May2019

Table 1.16 Change from Baseline in Height SDS at Week 52: ANCOVA Analysis, subgroup analysis  
ITT Population

Gender	Baseline		Week 52			TransCon hGH vs. Genotropin			
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value
<b>Male</b>									
TransCon hGH	86/86	-2.82 (0.707)	86/85	0.99 (0.464)	1.01 (0.038)	0.17 [0.047,0.303]	0.0077	0.28 [-0.084,0.642]	0.1016
Genotropin	46/46	-3.01 (0.922)	46/45	0.86 (0.435)	0.83 (0.052)				
<b>Female</b>									
TransCon hGH	19/19	-3.21 (1.283)	19/19	1.20 (0.605)	1.13 (0.063)	-0.13 [-0.354,0.093]	0.2398	0.11 [-0.659,0.874]	
Genotropin	10/10	-2.94 (0.853)	10/10	1.14 (0.501)	1.26 (0.087)				

An ANCOVA model with by visit change from baseline in height SDS as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS as covariates is fitted. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. Mean (SD) values are the observed data.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-hgsd-ancova-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:18 Page 2 of 6

Table 1.16 Change from Baseline in Height SDS at Week 52: ANCOVA Analysis, subgroup analysis  
ITT Population

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Genotropin			
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value
<b>&lt;=5 ng/mL</b>									
TransCon hGH	37/37	-3.06 (0.927)	37/37	1.13 (0.553)	1.23 (0.074)	0.17 [-0.065,0.396]	0.1557	0.21 [-0.334,0.756]	0.2569
Genotropin	21/21	-3.48 (1.177)	21/20	1.01 (0.603)	1.07 (0.100)				
<b>&gt;5 ng/mL</b>									
TransCon hGH	68/68	-2.79 (0.791)	68/67	0.97 (0.457)	1.00 (0.049)	0.11 [-0.017,0.245]	0.0882	0.27 [-0.141,0.680]	
Genotropin	35/35	-2.71 (0.523)	35/35	0.86 (0.343)	0.89 (0.060)				

An ANCOVA model with by visit change from baseline in height SDS as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS as covariates is fitted. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. Mean (SD) values are the observed data.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-hgsd-ancova-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:18 Page 3 of 6

Table 1.16 Change from Baseline in Height SDS at Week 52: ANCOVA Analysis, subgroup analysis  
ITT Population

Etiology and extend of GHD	Baseline		Week 52			TransCon hGH vs. Genotropin			
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	LS Mean <sup>c</sup> [95 %-CI]	Difference in p-value	Hedges'g [95 %-CI]	Interaction p-value
<b>Isolated Idiopathic</b>									
TransCon hGH	68/68	-2.71 (0.666)	68/67	0.91 (0.402)	0.94 (0.050)	0.11 [-0.015,0.235]	0.0837	0.36 [-0.047,0.769]	0.8826
Genotropin	37/37	-2.67 (0.673)	37/36	0.77 (0.385)	0.83 (0.058)				
<b>Isolated Organic</b>									
TransCon hGH	19/19	-2.95 (0.749)	19/19	1.12 (0.481)	1.15 (0.104)	0.06 [-0.282,0.401]	0.7210	-0.14 [-0.937,0.651]	
Genotropin	9/9	-3.86 (1.000)	9/9	1.19 (0.408)	1.09 (0.120)				
<b>Multiple Pituitary Hormone Deficiencies</b>									
TransCon hGH	18/18	-3.49 (1.236)	18/18	1.38 (0.651)	1.45 (0.118)	0.17 [-0.266,0.598]	0.4339	0.29 [-0.485,1.069]	
Genotropin	10/10	-3.43 (0.948)	10/10	1.20 (0.516)	1.28 (0.177)				

An ANCOVA model with by visit change from baseline in height SDS as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS as covariates is fitted. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. Mean (SD) values are the observed data.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-hgsd-ancova-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:18 Page 4 of 6

Table 1.16 Change from Baseline in Height SDS at Week 52: ANCOVA Analysis, subgroup analysis  
ITT Population

Region	Baseline		Week 52			TransCon hGH vs. Genotropin			
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value
North America									
TransCon hGH	27/27	-2.62 (0.660)	27/27	0.77 (0.388)	0.80 (0.091)	0.02 [-0.208,0.252]	0.8469	0.30 [-0.353,0.945]	0.8392
Genotropin	15/15	-2.71 (0.978)	15/14	0.65 (0.488)	0.78 (0.086)				
Europe									
TransCon hGH	66/66	-2.96 (0.917)	66/65	1.15 (0.519)	1.19 (0.052)	0.15 [-0.008,0.301]	0.0621	0.27 [-0.156,0.704]	
Genotropin	31/31	-2.84 (0.696)	31/31	1.01 (0.435)	1.05 (0.069)				
Rest of the World									
TransCon hGH	12/12	-3.10 (0.727)	12/12	0.96 (0.365)	1.12 (0.119)	0.15 [-0.206,0.515]	0.3776	-0.06 [-0.897,0.782]	
Genotropin	10/10	-3.90 (0.863)	10/10	0.98 (0.348)	0.97 (0.159)				

An ANCOVA model with by visit change from baseline in height SDS as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS as covariates is fitted. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. Mean (SD) values are the observed data.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-hgsd-ancova-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:18 Page 5 of 6

Table 1.16 Change from Baseline in Height SDS at Week 52: ANCOVA Analysis, subgroup analysis  
ITT Population

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Genotropin			
	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	N <sup>a</sup> /n <sup>b</sup>	Mean (SD)	LS-Mean (SE) <sup>c</sup>	Difference in LS Mean <sup>c</sup> [95 %-CI]	p-value	Hedges'g [95 %-CI]	Interaction p-value
<b>&lt; 8 ng/mL</b>									
TransCon hGH	76/76	-2.94 (0.852)	76/75	1.08 (0.524)	1.15 (0.049)	0.18 [0.035,0.317]	0.0151	0.31 [-0.075,0.696]	0.4208
Genotropin	41/41	-3.08 (1.001)	41/40	0.92 (0.509)	0.97 (0.064)				
<b>&gt;= 8 ng/mL</b>									
TransCon hGH	29/29	-2.75 (0.832)	29/29	0.90 (0.394)	0.95 (0.069)	0.04 [-0.148,0.222]	0.6906	-0.01 [-0.634,0.613]	
Genotropin	15/15	-2.77 (0.510)	15/15	0.90 (0.280)	0.92 (0.082)				

An ANCOVA model with by visit change from baseline in height SDS as the dependent variable, treatment and gender as factors, baseline age, baseline peak GH levels (log transformed) at stimulation test, subgroup, and baseline height SDS as covariates is fitted. a: Number of patients in the ITT population. b: Number of patients included in the analysis. c: LS-Mean as well as LS-Mean are determined with ANCOVA method. The interaction p-value is based on adding additional treatment by subgroup interaction term in the ANCOVA model. Mean (SD) values are the observed data.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-hgsd-ancova-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:16:18 Page 6 of 6

Table 1.22 Summary of Adverse Events, subgroup analysis by age  
Safety Population

Age: < 6 years

Number of Subjects with	TransCon hGH (N=25)	Genotropin (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Treatment emergent adverse events (TEAE)	20 (80.0%)	10 (71.4%)	30 (76.9%)	1.6000 [0.3506, 7.3023]	1.1200 [0.7622, 1.6459]	0.0857 [-0.1982, 0.3696]	0.9048
TEAEs related to study drug	1 (4.0%)	1 (7.1%)	2 (5.1%)		0.5475		
Serious AEs	0	0	0				0.9988
Serious AEs related to study drug	0	0	0				
TEAEs leading to any action on study drug	1 (4.0%)	0	1 (2.6%)				
TEAEs leading to discontinuation of study drug	0	0	0				
TEAEs leading to death	0	0	0				

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 1 of 2



Table 1.22 Summary of Adverse Events, subgroup analysis by age  
Safety Population

Age: >= 6 years

Number of Subjects with	TransCon hGH (N=80)	Genotropin (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Treatment emergent adverse events (TEAE)	61 (76.3%)	29 (69.0%)	90 (73.8%)	1.4392 [0.6260, 3.3089]	1.1043 [0.8717, 1.3990]	0.0720 [-0.0960, 0.2401]
TEAEs related to study drug	11 (13.8%)	9 (21.4%)	20 (16.4%)		0.3921	
Serious AEs	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	1 (1.3%)	1 (2.4%)	2 (1.6%)			
TEAEs leading to discontinuation of study drug	0	0	0			
TEAEs leading to death	0	0	0			

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 2 of 2

Table 1.23 Summary of Adverse Events, subgroup analysis by gender  
Safety Population

Male

Number of Subjects with	TransCon hGH (N=86)	Genotropin (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Treatment emergent adverse events (TEAE)	65 (75.6%)	33 (71.7%)	98 (74.2%)	1.2271 [0.5462, 2.7569]	1.0552 [0.8494, 1.3109]	0.0396 [-0.1192, 0.1985]	0.2803
TEAEs related to study drug	12 (14.0%)	9 (19.6%)	21 (15.9%)		0.6223		
Serious AEs	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984
Serious AEs related to study drug	0	0	0				
TEAEs leading to any action on study drug	2 (2.3%)	1 (2.2%)	3 (2.3%)				
TEAEs leading to discontinuation of study drug	0	0	0				
TEAEs leading to death	0	0	0				

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 1 of 2

Table 1.23 Summary of Adverse Events, subgroup analysis by gender  
Safety Population

Female	Lonapegsomatropin vs. Genotropina <sup>a</sup>					
	TransCon hGH (N=19)	Genotropin (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Number of Subjects with						
Treatment emergent adverse events (TEAE)	16 (84.2%)	6 (60.0%)	22 (75.9%)	3.5135 [0.5954, 20.7332]	1.3949 [0.8240, 2.3615]	0.2412 [-0.1092, 0.5917]
TEAEs related to study drug	0	1 (10.0%)	1 (3.4%)		0.1674	
Serious AEs	0	0	0			
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	0	0	0			
TEAEs leading to discontinuation of study drug	0	0	0			
TEAEs leading to death	0	0	0			

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 2 of 2

Table 1.24 Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata  
Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

Number of Subjects with	TransCon hGH (N=37)	Genotropin (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Treatment emergent adverse events (TEAE)	32 (86.5%)	17 (81.0%)	49 (84.5%)	1.4286 [0.3289, 6.2043]	1.0576 [0.8329, 1.3429]	0.0468 [-0.1510, 0.2447]	0.9889
TEAEs related to study drug	6 (16.2%)	6 (28.6%)	12 (20.7%)		0.6366		
Serious AEs	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640]	-0.0468 [-0.1373, 0.0437]	0.9430
Serious AEs related to study drug	0	0	0				
TEAEs leading to any action on study drug	0	1 (4.8%)	1 (1.7%)				
TEAEs leading to discontinuation of study drug	0	0	0				
TEAEs leading to death	0	0	0				

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 1 of 2

Table 1.24 Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata  
Safety Population

Number of Subjects with	TransCon hGH (N=68)	Genotropin (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Treatment emergent adverse events (TEAE)	49 (72.1%)	22 (62.9%)	71 (68.9%)	1.5258 [0.6407, 3.6334]	1.1469 [0.8538, 1.5405] 0.3432	0.0923 [-0.1003, 0.2849]
TEAEs related to study drug	6 (8.8%)	4 (11.4%)	10 (9.7%)			
Serious AEs	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	2 (2.9%)	0	2 (1.9%)			
TEAEs leading to discontinuation of study drug	0	0	0			
TEAEs leading to death	0	0	0			

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 2 of 2

Table 1.25 Summary of Adverse Events, subgroup analysis by etiology and extend of GHD  
Safety Population

Isolated idiopathic

Number of Subjects with	TransCon hGH (N=68)	Genotropin (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Treatment emergent adverse events (TEAE)	52 (76.5%)	26 (70.3%)	78 (74.3%)	1.3678 [0.5564, 3.3622]	1.0872 [0.8477, 1.3943]	0.0612 [-0.1177, 0.2402]	0.2233
TEAEs related to study drug	7 (10.3%)	5 (13.5%)	12 (11.4%)		0.4973		
Serious AEs	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9971
Serious AEs related to study drug	0	0	0				
TEAEs leading to any action on study drug	2 (2.9%)	0	2 (1.9%)				
TEAEs leading to discontinuation of study drug	0	0	0				
TEAEs leading to death	0	0	0				

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 1 of 3

Table 1.25 Summary of Adverse Events, subgroup analysis by etiology and extend of GHD  
Safety Population

Number of Subjects with	TransCon hGH (N=19)	Genotropin (N=9)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Treatment emergent adverse events (TEAE)	15 (78.9%)	4 (44.4%)	19 (67.9%)	3.4375 [0.6015, 19.6446]	1.6500 [0.7476, 3.6415]  0.1659	0.2889 [-0.1054, 0.6832]
TEAEs related to study drug	4 (21.1%)	3 (33.3%)	7 (25.0%)			
Serious AEs	0	0	0			
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	0	0	0			
TEAEs leading to discontinuation of study drug	0	0	0			
TEAEs leading to death	0	0	0			

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 2 of 3

Table 1.25 Summary of Adverse Events, subgroup analysis by etiology and extend of GHD  
Safety Population

Number of Subjects with	TransCon hGH (N=18)	Genotropin (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Treatment emergent adverse events (TEAE)	14 (77.8%)	9 (90.0%)	23 (82.1%)	0.3929 [0.0358, 4.3119]	0.8661 [0.6447, 1.1636]	-0.1232 [-0.3957, 0.1493]
TEAEs related to study drug	1 (5.6%)	2 (20.0%)	3 (10.7%)		0.4383	
Serious AEs	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484]	-0.1087 [-0.3025, 0.0851]
Serious AEs related to study drug	0	0	0		0.1432	
TEAEs leading to any action on study drug	0	1 (10.0%)	1 (3.6%)			
TEAEs leading to discontinuation of study drug	0	0	0			
TEAEs leading to death	0	0	0			

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 3 of 3



Table 1.26 Summary of Adverse Events, subgroup analysis by region  
Safety Population

Number of Subjects with	TransCon hGH (N=27)	Genotropin (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Treatment emergent adverse events (TEAE)	26 (96.3%)	14 (93.3%)	40 (95.2%)	4.6552 [0.1773, 122.2340]	1.0714 [0.9359, 1.2266]	0.0667 [-0.0596, 0.1929]	0.4024
TEAEs related to study drug	7 (25.9%)	3 (20.0%)	10 (23.8%)		0.2259		
Serious AEs	0	0	0				1.0000
Serious AEs related to study drug	0	0	0				
TEAEs leading to any action on study drug	1 (3.7%)	0	1 (2.4%)				
TEAEs leading to discontinuation of study drug	0	0	0				
TEAEs leading to death	0	0	0				

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 1 of 3

Table 1.26 Summary of Adverse Events, subgroup analysis by region  
Safety Population

Number of Subjects with	TransCon hGH (N=66)	Genotropin (N=31)	Total (N=97)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Treatment emergent adverse events (TEAE)	44 (66.7%)	19 (61.3%)	63 (64.9%)	1.4010 [0.5651, 3.4737]	1.1249 [0.8079, 1.5663] 0.4701	0.0752 [-0.1291, 0.2796]
TEAEs related to study drug	1 (1.5%)	3 (9.7%)	4 (4.1%)			
Serious AEs	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.3750 [0.0223, 6.3181]	0.3878 [0.0255, 5.8905] 0.4836	-0.0213 [-0.0916, 0.0490]
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	1 (1.5%)	1 (3.2%)	2 (2.1%)			
TEAEs leading to discontinuation of study drug	0	0	0			
TEAEs leading to death	0	0	0			

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 2 of 3

Table 1.26 Summary of Adverse Events, subgroup analysis by region  
Safety Population

Rest of the World	Lonapegsomatropin vs. Genotropina <sup>a</sup>					
	TransCon hGH (N=12)	Genotropin (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Treatment emergent adverse events (TEAE)	11 (91.7%)	6 (60.0%)	17 (77.3%)	6.8400 [0.6429, 72.7706]	1.5290 [0.8867, 2.6365]	0.3160 [-0.0300, 0.6620]
TEAEs related to study drug	4 (33.3%)	4 (40.0%)	8 (36.4%)		0.0936	
Serious AEs	0	0	0			
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	0	0	0			
TEAEs leading to discontinuation of study drug	0	0	0			
TEAEs leading to death	0	0	0			

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 3 of 3

Table 1.27 Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline  
Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

Number of Subjects with	TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Treatment emergent adverse events (TEAE)	60 (78.9%)	30 (73.2%)	90 (76.9%)	1.3784 [0.5691, 3.3390]	1.0795 [0.8675, 1.3432]	0.0581 [-0.1055, 0.2217]	0.7655
TEAEs related to study drug	10 (13.2%)	9 (22.0%)	19 (16.2%)		0.4798		
Serious AEs	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9988
Serious AEs related to study drug	0	0	0				
TEAEs leading to any action on study drug	2 (2.6%)	1 (2.4%)	3 (2.6%)				
TEAEs leading to discontinuation of study drug	0	0	0				
TEAEs leading to death	0	0	0				

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 1 of 2

Table 1.27 Summary of Adverse Events, subgroup analysis by peak stimulated GH concentration at baseline  
Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

Number of Subjects with	TransCon hGH (N=29)	Genotropin (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Treatment emergent adverse events (TEAE)	21 (72.4%)	9 (60.0%)	30 (68.2%)	1.7602 [0.4717, 6.5688]	1.2088 [0.7557, 1.9336]	0.1253 [-0.1711, 0.4217]
TEAEs related to study drug	2 (6.9%)	1 (6.7%)	3 (6.8%)		0.4080	
Serious AEs	0	0	0			
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	0	0	0			
TEAEs leading to discontinuation of study drug	0	0	0			
TEAEs leading to death	0	0	0			

a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-ae-sub.sas  
Data Extracted: 03May2019

v9.4 22FEB2023:17:40 Page 2 of 2

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)				
Any adverse event			20 (80.0%)	10 (71.4%)	30 (76.9%)				
		Mild	12 (48.0%)	5 (35.7%)	17 (43.6%)	1.6615 [0.4326, 6.3814]	1.3440 [0.5963, 3.0291]	0.1229 [-0.1955, 0.4412]	0.8693
		Moderate	8 (32.0%)	5 (35.7%)	13 (33.3%)	0.8471 [0.2133, 3.3632]	0.8960 [0.3622, 2.2166]	-0.0371 [-0.3477, 0.2734]	0.7077
		Severe	0	0	0		0.8158		0.9816
Infections and infestations			15 (60.0%)	9 (64.3%)	24 (61.5%)				
		Mild	11 (44.0%)	4 (28.6%)	15 (38.5%)	1.9643 [0.4830, 7.9887]	1.5400 [0.6022, 3.9381]	0.1543 [-0.1521, 0.4607]	0.3885
		Moderate	4 (16.0%)	5 (35.7%)	9 (23.1%)	0.3429 [0.0743, 1.5821]	0.4480 [0.1432, 1.4014]	-0.1971 [-0.4864, 0.0921]	0.3989
		Severe	0	0	0		0.1665		0.9816
	Pharyngitis		4 (16.0%)	3 (21.4%)	7 (17.9%)				
		Mild	3 (12.0%)	3 (21.4%)	6 (15.4%)	0.5000 [0.0863, 2.8957]	0.5600 [0.1300, 2.4124]	-0.0943 [-0.3441, 0.1556]	0.8453
							0.4397		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 1 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pharyngitis	Moderate	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9792
		Severe	0	0	0		0.4543		
	Nasopharyngitis	Mild	4 (16.0%)	1 (7.1%)	5 (12.8%)	2.4762 [0.2488, 24.6456]	2.2400 [0.2767, 18.1348]	0.0886 [-0.1085, 0.2857]	0.2665
		Moderate	4 (16.0%)	1 (7.1%)	5 (12.8%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292]	-0.0714 [-0.2063, 0.0635]	0.9604
	Respiratory tract infection	Severe	0	0	0		0.1814		
		Mild	4 (16.0%)	0	4 (10.3%)	6.0698 [0.3032, 121.5122]	5.1923 [0.2998, 89.9247]	0.1600 [0.0163, 0.3037]	0.9649
Moderate		4 (16.0%)	1 (7.1%)	5 (12.8%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292]	-0.0714 [-0.2063, 0.0635]	0.9582	
	Severe	0	0	0		0.1814			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 2 of 113





Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Tonsillitis		1 (4.0%)	1 (7.1%)	2 (5.1%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9792
		Moderate	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.4543 0.1923 [0.0083, 4.4292]	-0.0714 [-0.2063, 0.0635]	0.9755
	Upper respiratory tract infection	Severe	0	0	0		0.1814		
			2 (8.0%)	0	2 (5.1%)				
		Mild	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771]	0.0800 [-0.0263, 0.1863]	0.9779
	Viral infection	Moderate	0	0	0				0.9764
		Severe	0	0	0				
			2 (8.0%)	0	2 (5.1%)				
		Mild	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771]	0.0800 [-0.0263, 0.1863]	0.9985
		Moderate	0	0	0				0.9816
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 4 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Conjunctivitis		1 (4.0%)	0	1 (2.6%)				
		Mild	0	0	0				0.9816
		Moderate	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
	Ear infection	Severe	0	0	0				
		Mild	0	0	0				0.9988
		Moderate	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9998
	Eczema infected	Severe	0	0	0				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
		Moderate	0	0	0				
	Enteritis infectious	Severe	0	0	0				
		Mild	0	1 (7.1%)	1 (2.6%)				
			Mild	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 5 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Infections and infestations	Enteritis infectious	Moderate	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292]	-0.0714 [-0.2063, 0.0635]	0.9983
		Severe	0	0	0		0.1814		
	Gastroenteritis	Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292]	-0.0714 [-0.2063, 0.0635]	0.9769
		Moderate	0	0	0		0.1814		0.9750
	Gastroenteritis viral	Severe	0	0	0				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9989
	Laryngitis viral	Moderate	0	0	0		0.4543		
		Severe	0	0	0				
		Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292]	-0.0714 [-0.2063, 0.0635]	0.9755
		Moderate	0	0	0		0.1814		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 6 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pneumonia		1 (4.0%)	0	1 (2.6%)				
		Mild	0	0	0				
		Moderate	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9451
	Respiratory tract infection viral	Severe	0	0	0				
			0	1 (7.1%)	1 (2.6%)				
		Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292] 0.1814	-0.0714 [-0.2063, 0.0635]	0.9689
		Moderate	0	0	0				0.9816
		Severe	0	0	0				
		Rotavirus infection	1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 7 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Urinary tract infection		0	1 (7.1%)	1 (2.6%)				
		Mild	0	0	0				
		Moderate	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292]	-0.0714 [-0.2063, 0.0635]	0.9755
	Vulvitis	Severe	0	0	0		0.1814		
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9792
		Moderate	1 (4.0%)	0	1 (2.6%)		0.4543		
	Appendicitis	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Atypical pneumonia	Severe	0	0	0				0.9816
		Mild	0	0	0				
		Moderate	0	0	0				0.9816
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 8 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value		
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>
Infections and infestations	Conjunctivitis bacterial		0	0	0			
		Mild	0	0	0			0.9750
		Moderate	0	0	0			
	Croup infectious	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Cystitis	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			0.9816
	Enterobiasis	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			0.9999
	Helminthic infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			0.9988
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 9 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)		OR [95 %-CI] <sup>b</sup>
Infections and infestations	Hordeolum		0	0	0		
		Mild	0	0	0		0.9750
		Moderate	0	0	0		
	Infected bite	Severe	0	0	0		
			0	0	0		
		Mild	0	0	0		0.9816
	Influenza	Moderate	0	0	0		
		Severe	0	0	0		
			0	0	0		
	Molluscum contagiosum	Mild	0	0	0		0.9750
		Moderate	0	0	0		0.9816
		Severe	0	0	0		
	Otitis externa		0	0	0		
		Mild	0	0	0		
		Moderate	0	0	0		0.9816
		Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 10 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>							
Infections and infestations	Otitis media acute		0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0						0.9750		
	Pharyngitis streptococcal	Severe	0	0	0								
		Mild	0	0	0						0.9983		
		Moderate	0	0	0						0.9970		
	Pharyngotonsillitis	Severe	0	0	0								
		Mild	0	0	0						0.9750		
		Moderate	0	0	0						0.9816		
	Pulpitis dental	Severe	0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0								
	Tinea pedis	Severe	0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0								
			Severe	0	0	0							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 11 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Infections and infestations	Tooth abscess		0	0	0					
		Mild	0	0	0				0.9816	
		Moderate	0	0	0					
		Severe	0	0	0					
		Varicella	0	0	0					
			Mild	0	0	0				0.9816
			Moderate	0	0	0				0.9816
			Severe	0	0	0				
		Viral upper respiratory tract infection	0	0	0					
			Mild	0	0	0				0.9988
		Moderate	0	0	0					
		Severe	0	0	0					
Respiratory, thoracic and mediastinal disorders			8 (32.0%)	1 (7.1%)	9 (23.1%)					
		Mild	6 (24.0%)	1 (7.1%)	7 (17.9%)	4.1053 [0.4408, 38.2339]	3.3600 [0.4487, 25.1614]	0.1686 [-0.0464, 0.3836]	0.4487 0.1940	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 12 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771]	0.0800 [-0.0263, 0.1863]	0.9790
		Severe	0	0	0		0.2835		
		Mild	4 (16.0%)	0	4 (10.3%)	4.5111 [0.2167, 93.9115]	4.0385 [0.2235, 72.9741]	0.1200 [-0.0074, 0.2474]	0.9751
	Asthma	Moderate	3 (12.0%)	0	3 (7.7%)		0.1830		
		Severe	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9549
		Mild	0	0	0		0.4543		
	Epistaxis	Moderate	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9549
		Severe	0	0	0		0.4543		
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9687
			Moderate	0	0	0			0.9816
			Severe	0	0	0			0.9816

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 13 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Laryngospasm		1 (4.0%)	0	1 (2.6%)				
		Mild	0	0	0				
		Moderate	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
	Respiratory disorder	Severe	0	0	0				
		Mild	1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9687
	Rhinitis allergic	Moderate	0	0	0				0.9988
		Severe	0	0	0				
			0	1 (7.1%)	1 (2.6%)				
		Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292] 0.1814	-0.0714 [-0.2063, 0.0635]	0.9582
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 14 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Respiratory, thoracic and mediastinal disorders	Sinus congestion		1 (4.0%)	0	1 (2.6%)								
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.4543	0.9977			
		Moderate	0	0	0					0.9816			
	Allergic cough	Severe	0	0	0								
		Mild	0	0	0					0.9816			
		Moderate	0	0	0								
	Dyspnoea exertional	Severe	0	0	0								
		Mild	0	0	0								
		Moderate	0	0	0					0.9816			
	Nasal congestion	Severe	0	0	0								
		Mild	0	0	0					0.9988			
		Moderate	0	0	0					0.9816			
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 15 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value		
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			0.9816
	Rhinorrhoea	Severe	0	0	0			
		Mild	0	0	0			0.9764
		Moderate	0	0	0			
	Sleep apnoea syndrome	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			0.9816
	Wheezing	Severe	0	0	0			
		Mild	0	0	0			0.9988
		Moderate	0	0	0			0.9816
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 16 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25) / Genotropin n (N=14) / Total (N=39)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Gastrointestinal disorders			6 (24.0%)	0	6 (15.4%)				
		Mild	6 (24.0%)	0	6 (15.4%)	9.6667 [0.5031, 185.7364]	7.5000 [0.4536, 123.9982] 0.0492	0.2400 [0.0726, 0.4074]	0.9763
		Moderate	0	0	0				0.9970
		Severe	0	0	0				
		Dyspepsia							
		Mild	2 (8.0%)	0	2 (5.1%)				
		Mild	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771] 0.2835	0.0800 [-0.0263, 0.1863]	0.9740
		Moderate	0	0	0				
		Severe	0	0	0				
		Vomiting							
		Mild	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771] 0.2835	0.0800 [-0.0263, 0.1863]	0.9780
		Moderate	0	0	0				0.9750
		Severe	0	0	0				
		Constipation							
	Mild	1 (4.0%)	0	1 (2.6%)					
	Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9977	
	Moderate	0	0	0				0.9816	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 17 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Gastrointestinal disorders	Diarrhoea		1 (4.0%)	0	1 (2.6%)					
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9796	
		Moderate	0	0	0					
	Gastrointestinal motility disorder			1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792	
		Moderate	0	0	0					
	Lip swelling			1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792	
		Moderate	0	0	0					
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 18 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value			
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Abdominal discomfort		0	0	0				
		Mild	0	0	0				0.9740
		Moderate	0	0	0				
	Abdominal pain	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9999
	Abdominal pain upper	Moderate	0	0	0				0.9816
		Severe	0	0	0				
			0	0	0				
	Aphthous ulcer	Mild	0	0	0				0.9988
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastric disorder		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
	Severe	0	0	0					
		0	0	0					
	Mild	0	0	0				0.9816	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 19 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Gastrointestinal disorders	Nausea		0	0	0								
		Mild	0	0	0						0.9988		
		Moderate	0	0	0						0.9988		
	Toothache	Severe	0	0	0								
		Mild	0	0	0						0.9988		
		Moderate	0	0	0								
General disorders and administrative site conditions	Pyrexia	Severe	0	0	0								
		Mild	3 (12.0%)	1 (7.1%)	4 (10.3%)	1.7727 [0.1666, 18.8643]	1.6800 [0.1925, 14.6631] 0.6359	0.0486 [-0.1370, 0.2341]			0.6415		
		Moderate	0	0	0						0.9999		
	Pyrexia	Severe	0	0	0								
		Mild	2 (8.0%)	1 (7.1%)	3 (7.7%)	1.1304 [0.0933, 13.7020]	1.1200 [0.1112, 11.2786] 0.9242	0.0086 [-0.1632, 0.1804]			0.8974		
		Moderate	0	0	0						0.9754		
	Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
General disorders and administrative site conditions	Gait disturbance		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
		Moderate	0	0	0				
	Face oedema	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9750
	Fatigue	Severe	0	0	0				
		Mild	0	0	0				0.9988
		Moderate	0	0	0				
	Influenza like illness	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9750
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 21 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=25) Genotropin (N=14) Total (N=39)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
General disorders and administrative site conditions	Injection site atrophy	Mild	0	0	0				0.9816
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site swelling	Mild	0	0	0				0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site urticaria	Mild	0	0	0				0.9816
		Moderate	0	0	0				
		Severe	0	0	0				
	Medical device discomfort	Mild	0	0	0				0.9750
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 22 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
General disorders and administrative site conditions	Vaccination site pain		0	0	0								
		Mild	0	0	0						0.9750		
		Moderate	0	0	0								
		Severe	0	0	0								
Skin and subcutaneous tissue disorders	Cafe au lait spots		3 (12.0%)	1 (7.1%)	4 (10.3%)								
		Mild	3 (12.0%)	1 (7.1%)	4 (10.3%)	1.7727 [0.1666, 18.8643]	1.6800 [0.1925, 14.6631] 0.6359	0.0486 [-0.1370, 0.2341]	0.7919				
		Moderate	0	0	0				0.9970				
		Severe	0	0	0								
	Mild	1 (4.0%)	0	1 (2.6%)									
	Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792					
	Moderate	0	0	0									
	Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Dermatitis allergic		0	1 (7.1%)	1 (2.6%)				
		Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292] 0.1814	-0.0714 [-0.2063, 0.0635]	0.9755
		Moderate	0	0	0				
	Dermatitis contact	Severe	0	0	0				
			1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
	Keratosis pilaris	Moderate	0	0	0				
		Severe	0	0	0				
			1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 24 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>				
Skin and subcutaneous tissue disorders	Pityriasis alba		1 (4.0%)	0	1 (2.6%)										
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]					0.9792		
		Moderate	0	0	0		0.4543								
	Rash	Severe	0	0	0										
		Mild	1 (4.0%)	0	1 (2.6%)										
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]					0.9781		
	Eczema	Moderate	0	0	0										
		Severe	0	0	0										
		Mild	0	0	0										
	Petechiae	Moderate	0	0	0									0.9816	
		Severe	0	0	0										
		Mild	0	0	0									0.9816	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 25 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Skin and subcutaneous tissue disorders	Rash erythematous		0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0								
	Rash pruritic	Severe	0	0	0								
		Mild	0	0	0								
		Moderate	0	0	0						0.9750		
	Urticaria	Severe	0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0						0.9750		
	Blood and lymphatic system disorders	Severe	0	0	0								
		Mild	3 (12.0%)	0	3 (7.7%)								
		Mild	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771]	0.0800 [-0.0263, 0.1863]			0.9700		
						0.2835							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 26 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)		Genotropin n (N=14)		Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value		
			n	%	n	%		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>			
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	1	4.0%	0	0	1	2.6%	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9977	
		Severe	0		0	0	0						
	Anaemia	Mild	1	4.0%	0	0	1	2.6%	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9977	
		Moderate	1	4.0%	0	0	1	2.6%	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9792	
		Moderate	Mild	1	4.0%	0	0	1	2.6%	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9549
			Severe	0		0	0	0					
		Severe	Moderate	0		0	0	0					
			Severe	0		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 27 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders	Lymphadenopathy		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				0.9816
	Neutropenia	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9740
		Moderate	0	0	0				
		Severe	0	0	0				
Musculoskeletal and connective tissue disorders	1 (4.0%) 2 (14.3%) 3 (7.7%)								
	Mild	1 (4.0%)	2 (14.3%)	3 (7.7%)	0.2500 [0.0206, 3.0410]	0.2800 [0.0278, 2.8196]	-0.1029 [-0.3016, 0.0959]	0.3675	
	Moderate	0	0	0		0.2537		0.9740	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 28 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Arthralgia		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9759
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain in extremity		0	1 (7.1%)	1 (2.6%)				
		Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292] 0.1814	-0.0714 [-0.2063, 0.0635]	0.9758
		Moderate	0	0	0				0.9816
		Severe	0	0	0				
	Synovial cyst		0	1 (7.1%)	1 (2.6%)				
		Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292] 0.1814	-0.0714 [-0.2063, 0.0635]	0.9755
Moderate		0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 29 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction n p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>							
Musculoskeletal and connective tissue disorders	Arthritis reactive		0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0								
	Back pain	Severe	0	0	0								
		Mild	0	0	0								
		Moderate	0	0	0						0.9816		
	Musculoskeletal pain	Severe	0	0	0								
		Mild	0	0	0							0.9816	
		Moderate	0	0	0						0.9816		
	Neck mass	Severe	0	0	0								
		Mild	0	0	0							0.9816	
		Moderate	0	0	0								
	Neck pain	Severe	0	0	0								
		Mild	0	0	0							0.9988	
		Moderate	0	0	0								
			Severe	0	0	0							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 30 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Musculoskeletal and connective tissue disorders	Pain in jaw		0	0	0								
		Mild	0	0	0								
		Moderate	0	0	0							0.9816	
		Severe	0	0	0								
Endocrine disorders	Secondary hypothyroidism		1 (4.0%)	1 (7.1%)	2 (5.1%)								
		Mild	1 (4.0%)	1 (7.1%)	2 (5.1%)	0.5417 [0.0312, 9.3905]	0.5600 [0.0379, 8.2786] 0.6735	-0.0314 [-0.1867, 0.1238]		0.9488			
		Moderate	0	0	0					0.9740			
		Severe	0	0	0								
	Mild	1 (4.0%)	1 (7.1%)	2 (5.1%)	0.5417 [0.0312, 9.3905]	0.5600 [0.0379, 8.2786] 0.6735	-0.0314 [-0.1867, 0.1238]		0.5941				
	Moderate	0	0	0					0.9816				
	Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 31 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH vs. Genotropin			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			(N=25)	(N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Adrenal insufficiency		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9816
	Diabetes insipidus	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9988
	Moderate		0	0	0				
		Severe	0	0	0				
			0	0	0				
	Hypothyroidism		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
	Severe		0	0	0				
			0	0	0				
			0	0	0				
Secondary adrenocortical insufficiency		0	0	0					
	Mild	0	0	0				0.9988	
	Moderate	0	0	0					
Severe		0	0	0					
		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 32 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value	
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Injury, poisoning and procedural complications				2 (8.0%)	0	2 (5.1%)					
			Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9755	
			Moderate	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9759	
			Severe	0	0	0					
			Burns second degree	Mild	0	0	0				
				Moderate	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
				Severe	0	0	0				
			Contusion	Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
				Moderate	0	0	0				0.9816
				Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 33 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Injury, poisoning and procedural complications	Fall		1 (4.0%)	0	1 (2.6%)								
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.4543	0.9792			
		Moderate	0	0	0								
	Animal bite	Severe	0	0	0								
		Mild	0	0	0					0.9988			
		Moderate	0	0	0								
	Ankle fracture	Severe	0	0	0								
		Mild	0	0	0					0.9816			
		Moderate	0	0	0								
	Arthropod bite	Severe	0	0	0								
		Mild	0	0	0					0.9988			
		Moderate	0	0	0								
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 34 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>							
Injury, poisoning and procedural complications	Burns first degree		0	0	0										
		Mild	0	0	0								0.9750		
		Moderate	0	0	0										
	Concussion	Severe	0	0	0										
		Mild	0	0	0								0.9750		
		Moderate	0	0	0										
	Face injury	Severe	0	0	0										
		Mild	0	0	0								0.9816		
		Moderate	0	0	0										
	Head injury	Severe	0	0	0										
		Mild	0	0	0								0.9816		
		Moderate	0	0	0										
	Laceration	Severe	0	0	0										
		Mild	0	0	0								0.9816		
		Moderate	0	0	0										
		Severe	0	0	0										

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 35 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value			
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Ligament sprain		0	0	0				
		Mild	0	0	0				0.9816
		Moderate	0	0	0				
	Meniscus injury	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9750
	Muscle strain	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9816
	Post-traumatic pain	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9988
	Radius fracture	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9816
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 36 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>							
Injury, poisoning and procedural complications	Thermal burn		0	0	0										
		Mild	0	0	0									0.9750	
		Moderate	0	0	0										
	Upper limb fracture	Severe	0	0	0										
		Mild	0	0	0									0.9816	
		Moderate	0	0	0										
	Wrist fracture	Severe	0	0	0										
		Mild	0	0	0									0.9816	
		Moderate	0	0	0										
			Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 37 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations			2 (8.0%)	0	2 (5.1%)				
		Mild	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771] 0.2835	0.0800 [-0.0263, 0.1863]	0.9768
		Moderate	0	0	0				
		Severe	0	0	0				
		Eosinophil count increased	1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9977
		Moderate	0	0	0				
		Severe	0	0	0				
		Insulin-like growth factor increased	1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9977
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 38 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Investigations	Alanine aminotransferase increased		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
	Aspartate aminotransferase increased	Severe	0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
	Blood cortisol decreased	Severe	0	0	0				
		Mild	0	0	0				0.9816
		Moderate	0	0	0				
	Blood iron decreased	Severe	0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 39 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	
Investigations	Blood iron increased		0	0	0	
		Mild	0	0	0	0.9750
		Moderate	0	0	0	
		Severe	0	0	0	
	Blood thyroid stimulating hormone increased		0	0	0	
		Mild	0	0	0	0.9816
		Moderate	0	0	0	
		Severe	0	0	0	
	Cortisol free urine decreased		0	0	0	
		Mild	0	0	0	0.9816
		Moderate	0	0	0	
		Severe	0	0	0	
	Thyroxine decreased		0	0	0	
		Mild	0	0	0	0.9750
		Moderate	0	0	0	
Severe		0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 40 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Investigations	Transaminases increased		0	0	0				
		Mild	0	0	0				0.9816
		Moderate	0	0	0				
	White blood cell count decreased	Severe	0	0	0				
		Mild	0	0	0				0.9816
		Moderate	0	0	0				
	Psychiatric disorders	Severe	0	0	0				
		Mild	2 (8.0%)	0	2 (5.1%)				
		Moderate	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771]	0.0800 [-0.0263, 0.1863]	0.9753
	Severe	0	0	0		0.2835		0.9816	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 41 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Psychiatric disorders	Attention deficit/hyperactivity disorder		1 (4.0%)	0	1 (2.6%)								
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9549				
		Moderate	0	0	0								
	Enuresis	Severe	0	0	0								
		Mild	1 (4.0%)	0	1 (2.6%)								
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792				
	Affect lability	Moderate	0	0	0								
		Severe	0	0	0								
		Severe	0	0	0								
	Depressive symptom	Mild	0	0	0				0.9816				
		Moderate	0	0	0								
		Severe	0	0	0				0.9816				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 42 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Ear and labyrinth disorders	Ear pain		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9717
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
		Moderate	0	0	0				
Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 43 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	
Eye disorders	Astigmatism		0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	
		Severe	0	0	0	0.9816
	Conjunctivitis allergic		0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	0.9816
		Severe	0	0	0	
	Eye haemorrhage		0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	0.9816
		Severe	0	0	0	
	Hypermetropia		0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	0.9816
	Severe	0	0	0		
Myopia		0	0	0		
	Mild	0	0	0		
	Moderate	0	0	0	0.9750	
	Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 44 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)				
Eye disorders	Strabismus		0	0	0				
		Mild	0	0	0				0.9988
		Moderate	0	0	0				
		Severe	0	0	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9781
		Moderate	0	0	0				
		Severe	0	0	0				
		Osteoma	1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9792
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 45 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>							
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma		0	0	0										
		Mild	0	0	0									0.9999	
		Moderate	0	0	0										
		Severe	0	0	0										
Nervous system disorders	Headache		1 (4.0%)	0	1 (2.6%)										
		Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.4543	0.9741					
		Moderate	0	0	0					0.9992					
		Severe	0	0	0										
	Mild	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.4543	0.9768						
	Moderate	0	0	0					0.9992						
	Severe	0	0	0											

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 46 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=25) Genotropin n (N=14) Total (N=39)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction n p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Nervous system disorders	Dizziness		0	0	0				
		Mild	0	0	0				0.9999
		Moderate	0	0	0				
	Migraine	Severe	0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
	Post-traumatic headache	Severe	0	0	0				
		Mild	0	0	0				0.9988
		Moderate	0	0	0				
	Tremor	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9816
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 47 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>								
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value		
Reproductive system and breast disorders			0	1 (7.1%)	1 (2.6%)						
		Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292] 0.1814	-0.0714 [-0.2063, 0.0635]	0.9983		
		Moderate	0	0	0						
		Severe	0	0	0						
	Genital discomfort			0	1 (7.1%)	1 (2.6%)					
			Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292] 0.1814	-0.0714 [-0.2063, 0.0635]	0.9755	
			Moderate	0	0	0					
			Severe	0	0	0					
		Penile adhesion			0	1 (7.1%)	1 (2.6%)				
				Mild	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292] 0.1814	-0.0714 [-0.2063, 0.0635]	0.9983
			Moderate	0	0	0					
			Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 48 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=25)	Genotropin n (N=14)	Total (N=39)	
Cardiac disorders			0	0	0	
		Mild	0	0	0	0.9816
		Moderate	0	0	0	0.9816
		Severe	0	0	0	
	Sinoatrial block		0	0	0	
		Mild	0	0	0	0.9816
		Moderate	0	0	0	
		Severe	0	0	0	
	Sinus tachycardia		0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	0.9816
		Severe	0	0	0	
	Tachycardia		0	0	0	
		Mild	0	0	0	0.9816
		Moderate	0	0	0	
		Severe	0	0	0	
Hepatobiliary disorders			0	0	0	
		Mild	0	0	0	0.9750
		Moderate	0	0	0	
		Severe	0	0	0	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 49 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>							
Hepatobiliary disorders	Hepatomegaly		0	0	0								
		Mild	0	0	0						0.9750		
		Moderate	0	0	0								
		Severe	0	0	0								
Immune system disorders			0	0	0								
		Mild	0	0	0						0.9990		
		Moderate	0	0	0						0.9816		
	Allergy to animal		0	0	0								
		Mild	0	0	0						0.9740		
		Moderate	0	0	0								
	Hypersensitivity		0	0	0								
		Mild	0	0	0						0.9750		
		Moderate	0	0	0						0.9816		
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 50 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>							
Immune system disorders	Seasonal allergy		0	0	0								
		Mild	0	0	0						0.9987		
		Moderate	0	0	0								
		Severe	0	0	0								
Metabolism and nutrition disorders			0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0								
	Polydipsia		0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0								
		Severe	0	0	0								
Renal and urinary disorders			0	0	0								
		Mild	0	0	0						0.9740		
		Moderate	0	0	0								
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 51 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: < 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)			Genotropin n (N=14)			Total (N=39)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Renal and urinary disorders	Pollakiuria		0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0								
	Polyuria	Severe	0	0	0								
		Mild	0	0	0						0.9816		
		Moderate	0	0	0								
Vascular disorders	Hypotension	Severe	0	0	0								
		Mild	0	0	0						0.9740		
		Moderate	0	0	0								
	Hypotension	Severe	0	0	0								
		Mild	0	0	0						0.9740		
		Moderate	0	0	0								
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 52 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Any adverse event			61 (76.3%)	29 (69.0%)	90 (73.8%)			
	Mild		41 (51.3%)	15 (35.7%)	56 (45.9%)	1.8923 [0.8775, 4.0807]	1.4350 [0.9072, 2.2700] 0.1032	0.1554 [-0.0263, 0.3370]
	Moderate		19 (23.8%)	14 (33.3%)	33 (27.0%)	0.6230 [0.2736, 1.4182]	0.7125 [0.3987, 1.2733] 0.2595	-0.0958 [-0.2662, 0.0745]
	Severe		1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Infections and infestations		41 (51.3%)	23 (54.8%)	64 (52.5%)			
	Mild		28 (35.0%)	15 (35.7%)	43 (35.2%)	0.9692 [0.4440, 2.1158]	0.9800 [0.5921, 1.6219] 0.9377	-0.0071 [-0.1858, 0.1715]
	Moderate		12 (15.0%)	8 (19.0%)	20 (16.4%)	0.7500 [0.2801, 2.0079]	0.7875 [0.3493, 1.7754] 0.5677	-0.0405 [-0.1827, 0.1017]
	Severe		1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 53 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Nasopharyngitis		8 (10.0%)	6 (14.3%)	14 (11.5%)				
		Mild	7 (8.8%)	6 (14.3%)	13 (10.7%)	0.5753 [0.1801, 1.8375]	0.6125 [0.2199, 1.7062]	-0.0554 [-0.1780, 0.0673]	
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	0.3484 1.5926 [0.0663, 38.2649]	0.0125 [ -0.0118, 0.0368]	
	Pharyngitis	Severe	0	0	0		0.4687		
		Mild	6 (7.5%)	7 (16.7%)	13 (10.7%)	0.4054 [0.1268, 1.2961]	0.4500 [0.1615, 1.2535]	-0.0917 [-0.2183, 0.0350]	
		Moderate	0	0	0		0.1205		
	Upper respiratory tract infection	Severe	0	0	0				
		Mild	4 (5.0%)	5 (11.9%)	9 (7.4%)				
			Mild	4 (5.0%)	3 (7.1%)	7 (5.7%)	0.6842 [0.1458, 3.2105]	0.7000 [0.1643, 2.9830]	-0.0214 [-0.1128, 0.0699]

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 54 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Upper respiratory tract infection	Moderate	0	2 (4.8%)	2 (1.6%)	0.1006 [0.0047, 2.1455]	0.1062 [0.0052, 2.1621]	-0.0476 [-0.1120, 0.0168]
		Severe	0	0	0		0.0500	
	Pharyngitis streptococcal	Mild	3 (3.8%)	4 (9.5%)	7 (5.7%)	0.5128 [0.0696, 3.7767]	0.5250 [0.0767, 3.5955]	-0.0226 [-0.0955, 0.0503]
		Moderate	2 (2.5%)	2 (4.8%)	4 (3.3%)	0.2532 [0.0223, 2.8768]	0.2625 [0.0245, 2.8115]	-0.0351 [-0.1040, 0.0337]
	Ear infection	Severe	1 (1.3%)	2 (4.8%)	3 (2.5%)		0.2360	
		Mild	4 (5.0%)	1 (2.4%)	5 (4.1%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
		Moderate	1 (1.3%)	1 (2.4%)	2 (1.6%)		0.6416	
		Severe	3 (3.8%)	0	3 (2.5%)	3.8387 [0.1937, 76.0846]	3.7160 [0.1964, 70.2936]	0.0375 [-0.0041, 0.0791]
		Mild	0	0	0		0.2057	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 55 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Gastroenteritis		3 (3.8%)	2 (4.8%)	5 (4.1%)			
		Mild	3 (3.8%)	1 (2.4%)	4 (3.3%)	1.5974 [0.1610, 15.8482]	1.5750 [0.1690, 14.6787]	0.0137 [-0.0484, 0.0758]
		Moderate	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
	Respiratory tract infection	Severe	0	0	0		0.1675	
		Mild	3 (3.8%)	2 (4.8%)	5 (4.1%)	0.2532 [0.0223, 2.8768]	0.2625 [0.0245, 2.8115]	-0.0351 [-0.1040, 0.0337]
		Moderate	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520]	0.0250 [-0.0092, 0.0592]
Respiratory tract infection viral	Severe	0	0	0		0.3035		
	Mild	3 (3.8%)	1 (2.4%)	4 (3.3%)	1.0513 [0.0925, 11.9420]	1.0500 [0.0980, 11.2460]	0.0012 [-0.0562, 0.0586]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 56 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH			Lonapegsomatropin vs. Genotropina <sup>a</sup>			
			(N=80)	Genotropi n (N=42)	Total (N=122)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Respiratory tract infection viral	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]	
		Severe	0	0	0		0.4687		
		Viral infection	Mild	4 (5.0%)	0	4 (3.3%)			
			Mild	3 (3.8%)	0	3 (2.5%)	3.8387 [0.1937, 76.0846]	3.7160 [0.1964, 70.2936]	0.0375 [-0.0041, 0.0791]
			Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0		0.4687		
	Enterobiasis	Mild	2 (2.5%)	1 (2.4%)	3 (2.5%)	1.0513 [0.0925, 11.9420]	1.0500 [0.0980, 11.2460]	0.0012 [-0.0562, 0.0586]	
		Mild	2 (2.5%)	1 (2.4%)	3 (2.5%)		0.9680		
		Moderate	0	0	0				
		Severe	0	0	0				
		Rhinitis	Mild	3 (3.8%)	0	3 (2.5%)			
			Mild	3 (3.8%)	0	3 (2.5%)	3.8387 [0.1937, 76.0846]	3.7160 [0.1964, 70.2936]	0.0375 [-0.0041, 0.0791]
Moderate	0		0	0		0.2057			
Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 57 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Sinusitis		1 (1.3%)	2 (4.8%)	3 (2.5%)			
		Mild	0	2 (4.8%)	2 (1.6%)	0.1006 [0.0047, 2.1455]	0.1062 [0.0052, 2.1621]	-0.0476 [-0.1120, 0.0168]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
	Bronchitis	Severe	0	0	0		0.0500	
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Moderate	1 (1.3%)	0	1 (0.8%)		0.4687	
	Enteritis infectious	Severe	0	0	0		0.1770	-0.0238
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
		Moderate	0	1 (2.4%)	1 (0.8%)		0.1675	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 58 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Enteritis and infectious	Moderate	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
		Severe	0	0	0		0.1675	
	Gastroenteritis viral	Mild	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520]	0.0250 [-0.0092, 0.0592]
		Moderate	2 (2.5%)	0	2 (1.6%)		0.3035	
		Severe	0	0	0			
	Helminthic infection	Mild	0	0	0			
		Moderate	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
		Severe	0	0	0		0.6416	
	Influenza	Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
		Severe	0	1 (2.4%)	1 (0.8%)		0.1675	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 59 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Influenza	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0		0.4687	
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
	Otitis media acute	Moderate	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
		Severe	0	0	0		0.1675	
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
	Pharyngotonsillitis	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0		0.4687	
		Mild	0	2 (4.8%)	2 (1.6%)			
	Pneumonia	Mild	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 60 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Pneumonia	Moderate	0	2 (4.8%)	2 (1.6%)	0.1006 [0.0047, 2.1455]	0.1062 [0.0052, 2.1621]	-0.0476 [-0.1120, 0.0168]
		Severe	0	0	0		0.0500	
	Varicella	Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
	Viral upper respiratory tract infection	Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
		Severe	0	0	0		0.6416	
	Appendicitis	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 61 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Appendicitis	Severe	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]	
	Atypical pneumonia			1 (1.3%)	0	1 (0.8%)			
		Mild		0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]	
	Conjunctivitis	Severe		0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]	
		Moderate		0	0	0			
	Conjunctivitis bacterial	Severe		0	0	0			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]	
		Moderate		0	0	0			
		Severe		0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 62 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Croup and infectious		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)			
		Moderate	0	0	0			
	Cystitis	Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038	1.5926	0.0125
		Moderate	1 (1.3%)	0	1 (0.8%)	[0.0639, 40.2280]	[0.0663, 38.2649]	[-0.0118, 0.0368]
	Hordeolum	Severe	0	0	0		0.4687	
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718	0.1770	-0.0238
		Moderate	0	1 (2.4%)	1 (0.8%)	[0.0068, 4.3114]	[0.0074, 4.2517]	[-0.0699, 0.0223]
	Infected bite	Severe	0	0	0		0.1675	
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038	1.5926	0.0125
		Moderate	1 (1.3%)	0	1 (0.8%)	[0.0639, 40.2280]	[0.0663, 38.2649]	[-0.0118, 0.0368]
			Severe	0	0		0.4687	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 63 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropi n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Molluscum contagiosum		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Otitis externa	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	0	0	0			
	Pulpitis dental	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Tinea pedis	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 64 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Tooth abscess		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Eczema infected	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Laryngitis viral	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Rotavirus infection	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 65 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)			Genotropin n (N=42)			Total (N=122)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR	[95 %-CI] <sup>b</sup>	RR	[95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD	[95 %-CI] <sup>b</sup>					
Infections and infestations	Tonsillitis		0	0	0									
		Mild	0	0	0									
		Moderate	0	0	0									
	Urinary tract infection	Severe	0	0	0									
		Mild	0	0	0									
		Moderate	0	0	0									
	Vulvitis	Severe	0	0	0									
		Mild	0	0	0									
		Moderate	0	0	0									
	Gastrointestinal disorders	Severe	0	0	0									
		Mild	18 (22.5%)	8 (19.0%)	26 (21.3%)	1.6190	[0.5857, 4.4756]	1.4875	[0.6342, 3.4889]	0.0696	[-0.0690, 0.2083]	0.3521		
		Moderate	1 (1.3%)	2 (4.8%)	3 (2.5%)	0.2532	[0.0223, 2.8768]	0.2625	[0.0245, 2.8115]	-0.0351	[-0.1040, 0.0337]	0.2360		
Severe		0	0	0										

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 66 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Vomiting		7 (8.8%)	3 (7.1%)	10 (8.2%)			
		Mild	7 (8.8%)	2 (4.8%)	9 (7.4%)	1.9178 [0.3803, 9.6722]	1.8375 [0.3993, 8.4558]	0.0399 [-0.0495, 0.1292]
		Moderate	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
	Diarrhoea	Severe	0	0	0		0.4252 0.1675	
		Mild	5 (6.3%)	3 (7.1%)	8 (6.6%)	0.8667 [0.1967, 3.8176]	0.8750 [0.2197, 3.4842]	-0.0089 [-0.1032, 0.0853]
		Moderate	0	0	0		0.8505	
	Nausea	Severe	0	0	0			
		Mild	4 (5.0%)	2 (4.8%)	6 (4.9%)	1.5974 [0.1610, 15.8482]	1.5750 [0.1690, 14.6787]	0.0137 [-0.0484, 0.0758]
		Moderate	3 (3.8%)	1 (2.4%)	4 (3.3%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
		Severe	0	0	0		0.6416	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 67 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Abdominal pain		3 (3.8%)	1 (2.4%)	4 (3.3%)			
		Mild	2 (2.5%)	1 (2.4%)	3 (2.5%)	1.0513 [0.0925, 11.9420]	1.0500 [0.0980, 11.2460]	0.0012 [-0.0562, 0.0586]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0		0.4687	
	Abdominal pain upper		3 (3.8%)	1 (2.4%)	4 (3.3%)			
		Mild	3 (3.8%)	1 (2.4%)	4 (3.3%)	1.5974 [0.1610, 15.8482]	1.5750 [0.1690, 14.6787]	0.0137 [-0.0484, 0.0758]
		Moderate	0	0	0		0.6878	
		Severe	0	0	0			
	Abdominal discomfort		2 (2.5%)	0	2 (1.6%)			
		Mild	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520]	0.0250 [-0.0092, 0.0592]
		Moderate	0	0	0		0.3035	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 68 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Constipation		2 (2.5%)	0	2 (1.6%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Toothache	Severe	0	0	0			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839] 0.6416	-0.0113 [-0.0634, 0.0408]
		Moderate	0	0	0			
	Aphthous ulcer	Severe	0	0	0			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 69 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Gastric disorder		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0		0.4687	
	Dyspepsia	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Gastrointestinal motility disorder	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Lip swelling	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 70 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Cough		19 (23.8%)	7 (16.7%)	26 (21.3%)			
		Mild	14 (17.5%)	5 (11.9%)	19 (15.6%)	1.5697 [0.5238, 4.7043]	1.4700 [0.5683, 3.8024] 0.4200	0.0560 [-0.0726, 0.1845]
		Moderate	5 (6.3%)	2 (4.8%)	7 (5.7%)	1.3333 [0.2475, 7.1836]	1.3125 [0.2659, 6.4796] 0.7381	0.0149 [-0.0686, 0.0983]
		Severe	0	0	0			
		Mild	6 (7.5%)	4 (9.5%)	10 (8.2%)	1.0541 [0.2499, 4.4450]	1.0500 [0.2764, 3.9885] 0.9431	0.0036 [-0.0934, 0.1005]
		Moderate	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Severe	0	0	0			
		Mild	2 (2.5%)	2 (4.8%)	4 (3.3%)			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839] 0.6416	-0.0113 [-0.0634, 0.0408]
		Respiratory disorder						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 71 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
		Severe	0	0	0		0.6416	
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
	Epistaxis	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0		0.4687	
		Mild	2 (2.5%)	1 (2.4%)	3 (2.5%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
Nasal congestion	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]	
	Severe	0	0	0		0.4687		
	Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 72 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Wheezing		2 (2.5%)	1 (2.4%)	3 (2.5%)			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
	Asthma	Severe	0	0	0		0.6416	
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
	Rhinitis allergic	Severe	0	0	0		0.4687	
		Mild	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520]	0.0250 [-0.0092, 0.0592]
		Moderate	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520]	0.0250 [-0.0092, 0.0592]
		Severe	0	0	0		0.3035	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 73 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		0	2 (4.8%)	2 (1.6%)			
		Mild	0	2 (4.8%)	2 (1.6%)	0.1006 [0.0047, 2.1455]	0.1062 [0.0052, 2.1621] 0.0500	-0.0476 [-0.1120, 0.0168]
		Moderate	0	0	0			
	Sinus congestion	Severe	0	0	0			
			2 (2.5%)	0	2 (1.6%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Allergic cough	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 74 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		1 (1.3%)	0	1 (0.8%)			
		Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Paranasal sinus discomfort	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
	Sleep apnoea syndrome	Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 75 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)			Genotropin n (N=42)			Total (N=122)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0	0	0									
		Mild	0	0	0									
		Moderate	0	0	0									
		Severe	0	0	0									
General disorders and administration site conditions			15 (18.8%)	8 (19.0%)	23 (18.9%)									
		Mild	11 (13.8%)	6 (14.3%)	17 (13.9%)	0.9565	0.9625	0.9356	-0.0054	[0.3270, 2.7977]	[0.3828, 2.4199]	[-0.1353, 0.1246]		
		Moderate	4 (5.0%)	2 (4.8%)	6 (4.9%)	1.0526	1.0500	0.9541	0.0024	[0.1848, 5.9973]	[0.2005, 5.4990]	[-0.0778, 0.0826]		
		Severe	0	0	0									
Pyrexia			14 (17.5%)	4 (9.5%)	18 (14.8%)									
		Mild	10 (12.5%)	4 (9.5%)	14 (11.5%)	1.3571	1.3125	0.6255	0.0298	[0.3987, 4.6197]	[0.4379, 3.9341]	[-0.0848, 0.1444]		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 76 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=80)	n (N=42)	Total (N=122)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions	Pyrexia	Moderate	4 (5.0%)	0	4 (3.3%)	5.0000 [0.2628, 95.1203]	4.7778 [0.2634, 86.6796]	0.0500 [0.0022, 0.0978]
		Severe	0	0	0		0.1423	
		Fatigue	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
	Face oedema	Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)		0.6416	
		Moderate	0	0	0			
		Severe	0	0	0			
	Influenza like illness	Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0		0.1675	
		Severe	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
			Severe	0	0	0		0.1675

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 77 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and site administration site conditions	Injection site swelling		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Injection site swelling	Severe	0	0	0			
			0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
	Injection site urticaria	Moderate	0	0	0			
		Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 78 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and device administration site conditions	Medical		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
	Vaccination site pain	Severe	0	0	0			
			0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
	Gait disturbance	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 79 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders			13 (16.3%)	9 (21.4%)	22 (18.0%)			
		Mild	9 (11.3%)	6 (14.3%)	15 (12.3%)	0.7606 [0.2511, 2.3034]	0.7875 [0.3006, 2.0631]	-0.0304 [-0.1568, 0.0961]
		Moderate	4 (5.0%)	3 (7.1%)	7 (5.7%)	0.6842 [0.1458, 3.2105]	0.6290 [0.1643, 2.9830]	-0.0214 [-0.1128, 0.0699]
		Severe	0	0	0		0.6301	
	Headache		12 (15.0%)	7 (16.7%)	19 (15.6%)			
		Mild	8 (10.0%)	4 (9.5%)	12 (9.8%)	1.0556 [0.2985, 3.7322]	1.0500 [0.3356, 3.2852]	0.0048 [-0.1057, 0.1152]
		Moderate	4 (5.0%)	3 (7.1%)	7 (5.7%)	0.6842 [0.1458, 3.2105]	0.7000 [0.1643, 2.9830]	-0.0214 [-0.1128, 0.0699]
		Severe	0	0	0		0.6301	
	Dizziness		2 (2.5%)	1 (2.4%)	3 (2.5%)			
		Mild	2 (2.5%)	1 (2.4%)	3 (2.5%)	1.0513 [0.0925, 11.9420]	1.0500 [0.0980, 11.2460]	0.0012 [-0.0562, 0.0586]
	Moderate	0	0	0		0.9680		
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 80 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders	Post-traumatic headache		1 (1.3%)	1 (2.4%)	2 (1.6%)			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839] 0.6416	-0.0113 [-0.0634, 0.0408]
		Moderate	0	0	0			
	Migraine	Severe	0	0	0			
			0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
	Tremor	Moderate	0	0	0			
		Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 81 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications			12 (15.0%)	6 (14.3%)	18 (14.8%)			
		Mild	8 (10.0%)	5 (11.9%)	13 (10.7%)	0.8222 [0.2512, 2.6908]	0.8400 [0.2930, 2.4078]	-0.0190 [-0.1370, 0.0989]
		Moderate	4 (5.0%)	1 (2.4%)	5 (4.1%)	2.1579 [0.2334, 19.9476]	2.1000 [0.2424, 18.1957]	0.0262 [-0.0402, 0.0926]
		Severe	0	0	0		0.7470 0.4899	
		Animal bite						
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
		Moderate	0	0	0		0.6416	
		Severe	0	0	0			
		Arthropod bite						
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]	-0.0113 [-0.0634, 0.0408]
	Moderate	0	0	0		0.6416		
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 82 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Post-traumatic pain		1 (1.3%)	1 (2.4%)	2 (1.6%)			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839] 0.6416	-0.0113 [-0.0634, 0.0408]
		Moderate	0	0	0			
	Ankle fracture	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	0	0	0			
	Burns first degree	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
			0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 83 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Concussion		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
	Contusion	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	0	0	0			
	Face injury	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
	Head injury	Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
			1 (1.3%)	0	1 (0.8%)			
		0	0	0				
		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 84 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Laceration		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Ligament sprain	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Meniscus injury	Moderate	0	0	0			
		Severe	0	0	0			
			0	1 (2.4%)	1 (0.8%)			
	Muscle strain	Mild	0	0	0			
		Moderate	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Severe	0	0	0			
		1 (1.3%)	0	1 (0.8%)				
		Mild	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 85 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Muscle strain	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0		0.4687	
	Radius fracture	Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0		0.4687	
	Thermal burn	Severe	0	0	0			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
	Upper limb fracture	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0		0.4687	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 86 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and fracture procedural complications	Wrist		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Burns second degree	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Fall	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Endocrine disorders	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
			8 (10.0%)	5 (11.9%)	13 (10.7%)			
	Mild	6 (7.5%)	5 (11.9%)	11 (9.0%)	0.6000 [0.1718, 2.0957]	0.6300 [0.2042, 1.9435] 0.4215	-0.0440 [-0.1577, 0.0696]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 87 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Endocrine disorders	Secondary hypothyroidism	Moderate	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520] 0.3035	0.0250 [-0.0092, 0.0592]
		Severe	0	0	0			
		Mild	6 (7.5%)	2 (4.8%)	8 (6.6%)			
	Diabetes insipidus	Mild	5 (6.3%)	2 (4.8%)	7 (5.7%)	1.3333 [0.2475, 7.1836]	1.3125 [0.2659, 6.4796] 0.7381	0.0149 [-0.0686, 0.0983]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839] 0.6416	-0.0113 [-0.0634, 0.0408]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 88 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Endocrine disorders	Secondary adrenocortical insufficiency		1 (1.3%)	1 (2.4%)	2 (1.6%)			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839] 0.6416	-0.0113 [-0.0634, 0.0408]
		Moderate	0	0	0			
		Severe	0	0	0			
	Adrenal insufficiency		1 (1.3%)	0	1 (0.8%)			
		Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
	Hypothyroidism		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 89 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders			9 (11.3%)	4 (9.5%)	13 (10.7%)			
		Mild	7 (8.8%)	4 (9.5%)	11 (9.0%)	0.9110 [0.2509, 3.3077]	0.9188 [0.2851, 2.9612]	-0.0077 [-0.1160, 0.1005]
		Moderate	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520]	0.0250 [-0.0092, 0.0592]
	Pain in extremity	Severe	0	0	0		0.8877 0.3035	
		Mild	4 (5.0%)	3 (7.1%)	7 (5.7%)	0.5065 [0.0977, 2.6268]	0.5250 [0.1108, 2.4887]	-0.0339 [-0.1222, 0.0544]
		Moderate	3 (3.8%)	3 (7.1%)	6 (4.9%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
	Arthralgia	Severe	1 (1.3%)	0	1 (0.8%)		0.4122 0.4687	
		Mild	4 (5.0%)	1 (2.4%)	5 (4.1%)	2.1579 [0.2334, 19.9476]	2.1000 [0.2424, 18.1957]	0.0262 [-0.0402, 0.0926]
		Moderate	4 (5.0%)	1 (2.4%)	5 (4.1%)			
		Severe	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		2 (2.5%)	0	2 (1.6%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Neck pain	Severe	0	0	0			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839] 0.6416	-0.0113 [-0.0634, 0.0408]
		Moderate	0	0	0			
	Arthritis reactive	Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 91 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Back pain		1 (1.3%)	0	1 (0.8%)			
		Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Neck mass	Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Pain in jaw	Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Synovial cyst	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 92 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Immune system disorders	Mild		7 (8.8%)	2 (4.8%)	9 (7.4%)			
			6 (7.5%)	2 (4.8%)	8 (6.6%)	1.6216 [0.3127, 8.4090]	1.5750 [0.3323, 7.4661]	0.0274 [-0.0591, 0.1139]
							0.5632	
	Moderate		1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
							0.4687	
	Severe		0	0	0			
			4 (5.0%)	1 (2.4%)	5 (4.1%)			
	Seasonal allergy	Mild	4 (5.0%)	1 (2.4%)	5 (4.1%)	2.1579 [0.2334, 19.9476]	2.1000 [0.2424, 18.1957]	0.0262 [-0.0402, 0.0926]
							0.4899	
Allergy to animal	Mild	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520]	0.0250 [-0.0092, 0.0592]	
						0.3035		
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 93 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Immune system disorders	Hypersensitivity		1 (1.3%)	1 (2.4%)	2 (1.6%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]
	Severe	0	0	0		0.4687		
Investigations			6 (7.5%)	3 (7.1%)	9 (7.4%)			
		Mild	6 (7.5%)	3 (7.1%)	9 (7.4%)	1.0541 [0.2499, 4.4450]	1.0500 [0.2764, 3.9885]	0.0036 [-0.0934, 0.1005]
		Moderate	0	0	0		0.9431	
	Severe	0	0	0				
Alanine aminotransferase increased			0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0		0.1675	
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 94 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Aspartate aminotransferase increased		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
	Blood cortisol decreased	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Blood iron decreased	Moderate	0	0	0			
		Severe	0	0	0			
			0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 95 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Blood iron increased		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
	Blood thyroid stimulating hormone increased	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Cortisol free urine decreased	Moderate	0	0	0			
		Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 96 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Eosinophil count increased		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Insulin-like growth factor increased	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Thyroxine decreased	Moderate	0	0	0			
		Severe	0	0	0			
			0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 97 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Transaminases increased		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	White blood cell count decreased	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Skin and subcutaneous tissue disorders	Severe	0	0	0			
			6 (7.5%)	3 (7.1%)	9 (7.4%)			
		Mild	5 (6.3%)	1 (2.4%)	6 (4.9%)	2.7333 [0.3088, 24.1925]	2.6250 [0.3169, 21.7450] 0.3497	0.0387 [-0.0316, 0.1090]
Moderate		1 (1.3%)	2 (4.8%)	3 (2.5%)	0.2532 [0.0223, 2.8768]	0.2625 [0.0245, 2.8115] 0.2360	-0.0351 [-0.1040, 0.0337]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 98 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Rash		2 (2.5%)	1 (2.4%)	3 (2.5%)			
		Mild	2 (2.5%)	1 (2.4%)	3 (2.5%)	1.0513 [0.0925, 11.9420]	1.0500 [0.0980, 11.2460] 0.9680	0.0012 [-0.0562, 0.0586]
		Moderate	0	0	0			
	Urticaria	Severe	0	0	0			
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	1 (1.3%)	0	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
	Eczema	Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Severe	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]	
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 99 of 113



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Petechiae		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Rash erythematous	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Rash pruritic	Moderate	0	0	0			
		Severe	0	0	0			
			0	1 (2.4%)	1 (0.8%)			
		Mild	0	0	0			
		Moderate	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]
		Severe	0	0	0		0.1675	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 100 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=80)	n (N=42)	Total (N=122)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Cafe au lait spots		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Dermatitis allergic	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Dermatitis contact	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Keratosis pilaris	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pityriasis alba		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 101 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Eye disorders	Strabismus	Mild	5 (6.3%)	2 (4.8%)	7 (5.7%)	1.3333 [0.2475, 7.1836]	1.3125 [0.2659, 6.4796] 0.7381	0.0149 [-0.0686, 0.0983]
		Moderate	0	0	0			
		Severe	0	0	0			
	Astigmatism	Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839] 0.6416	-0.0113 [-0.0634, 0.0408]
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis allergic	Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 102 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Eye disorders	Eye haemorrhage		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypermetropia		1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Myopia		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye swelling		0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				
Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 103 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders			4 (5.0%)	2 (4.8%)	6 (4.9%)				
		Mild	3 (3.8%)	2 (4.8%)	5 (4.1%)	0.7792 [0.1251, 4.8552]	0.7875 [0.1369, 4.5308]	-0.0101 [-0.0868, 0.0666]	
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	0.7897 1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]	
		Severe	0	0	0		0.4687		
		Lymphadenopathy		1 (1.3%)	1 (2.4%)	2 (1.6%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]	
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	0.1675 1.5926 [0.0663, 38.2649]	0.0125 [-0.0118, 0.0368]	
		Severe	0	0	0		0.4687		
		Neutropenia		2 (2.5%)	0	2 (1.6%)			
		Mild	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520]	0.0250 [-0.0092, 0.0592]	
	Moderate	0	0	0		0.3035			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 104 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Blood and lymphatic system disorders	Anaemia		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
	Iron deficiency anaemia	Severe	0	0	0			
			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
	Ear and labyrinth disorders	Severe	0	0	0			
			3 (3.8%)	0	3 (2.5%)			
		Mild	3 (3.8%)	0	3 (2.5%)	3.8387 [0.1937, 76.0846]	3.7160 [0.1964, 70.2936] 0.2057	0.0375 [-0.0041, 0.0791]
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 105 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Ear and labyrinth disorders	Ear pain		3 (3.8%)	0	3 (2.5%)			
		Mild	3 (3.8%)	0	3 (2.5%)	3.8387 [0.1937, 76.0846]	3.7160 [0.1964, 70.2936] 0.2057	0.0375 [-0.0041, 0.0791]
		Moderate	0	0	0			
		Severe	0	0	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			2 (2.5%)	1 (2.4%)	3 (2.5%)			
		Mild	2 (2.5%)	1 (2.4%)	3 (2.5%)	1.0513 [0.0925, 11.9420]	1.0500 [0.0980, 11.2460] 0.9680	0.0012 [-0.0562, 0.0586]
		Moderate	0	0	0			
		Severe	0	0	0			
Skin papilloma			2 (2.5%)	1 (2.4%)	3 (2.5%)			
		Mild	2 (2.5%)	1 (2.4%)	3 (2.5%)	1.0513 [0.0925, 11.9420]	1.0500 [0.0980, 11.2460] 0.9680	0.0012 [-0.0562, 0.0586]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 106 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)			Genotropin n (N=42)			Total (N=122)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0	0	0									
		Mild	0	0	0									
		Moderate	0	0	0									
		Severe	0	0	0									
Psychiatric disorders	Affect lability		2 (2.5%)	1 (2.4%)	3 (2.5%)									
		Mild	1 (1.3%)	1 (2.4%)	2 (1.6%)	0.5190 [0.0316, 8.5121]	0.5250 [0.0337, 8.1839]		-0.0113 [-0.0634, 0.0408]					
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.6416	0.0125 [-0.0118, 0.0368]					
		Severe	0	0	0									
	Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649]	0.4687	0.0125 [-0.0118, 0.0368]						
	Moderate	0	0	0										
	Severe	0	0	0										

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Psychiatric disorders	Attention deficit/hyperactivity disorder		0	1 (2.4%)	1 (0.8%)				
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Depressive symptom		1 (1.3%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]	
		Severe	0	0	0				
	Enuresis			0	0	0			
		Mild	0	0	0				
Moderate		0	0	0					
Severe		0	0	0					
Cardiac disorders			2 (2.5%)	0	2 (1.6%)				
	Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 108 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Cardiac disorders	Sinoatrial block	Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Sinus tachycardia	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)			
		Moderate	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
	Tachycardia	Severe	0	0	0			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			
		Moderate	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 109 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Renal and urinary disorders			2 (2.5%)	0	2 (1.6%)			
		Mild	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520] 0.3035	0.0250 [-0.0092, 0.0592]
		Moderate	0	0	0			
		Severe	0	0	0			
		Pollakiuria						
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			
		Polyuria						
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 110 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age  
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Vascular disorders			2 (2.5%)	0	2 (1.6%)				
		Mild	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520] 0.3035	0.0250 [-0.0092, 0.0592]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Hypotension		2 (2.5%)	0	2 (1.6%)			
		Mild	2 (2.5%)	0	2 (1.6%)	2.7070 [0.1270, 57.6888]	2.6543 [0.1303, 54.0520] 0.3035	0.0250 [-0.0092, 0.0592]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Hepatobiliary disorders			0	1 (2.4%)	1 (0.8%)			
			Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0				
		Severe	0	0	0				
		Hepatomegaly		0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 111 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)	Genotropin n (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Metabolism and nutrition disorders			1 (1.3%)	0	1 (0.8%)			
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			
		Polydipsia						
		Mild	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]
		Moderate	0	0	0			
		Severe	0	0	0			
Reproductive system and breast disorders			0	1 (2.4%)	1 (0.8%)			
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 112 of 113

Table 1.29 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by age Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	Severity	TransCon hGH (N=80)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			
			Genotropi n (N=42)	Total (N=122)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Reproductive system and breast disorders	Penile adhesion		0	1 (2.4%)	1 (0.8%)				
		Mild	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517]	-0.0238 [-0.0699, 0.0223]	
		Moderate	0	0	0		0.1675		
		Severe	0	0	0				
	Genital discomfort			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 113 of 113

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
Any adverse event			65 (75.6%)	33 (71.7%)	98 (74.2%)				
	Mild		43 (50.0%)	16 (34.8%)	59 (44.7%)	1.8884 [0.9000, 3.9622]	1.4427 [0.9206, 2.2609]	0.1537 [-0.0198, 0.3271]	0.8933
	Moderate		21 (24.4%)	17 (37.0%)	38 (28.8%)	0.5537 [0.2556, 1.1996]	0.6621 [0.3904, 1.1230]	-0.1253 [-0.2924, 0.0418]	0.2324
	Severe		1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
Infections and infestations			44 (51.2%)	27 (58.7%)	71 (53.8%)				
	Mild		32 (37.2%)	15 (32.6%)	47 (35.6%)	1.2394 [0.5827, 2.6359]	1.1500 [0.7002, 1.8889]	0.0490 [-0.1212, 0.2192]	0.7055
	Moderate		11 (12.8%)	12 (26.1%)	23 (17.4%)	0.4151 [0.1664, 1.0354]	0.4880 [0.2321, 1.0262]	-0.1331 [-0.2784, 0.0122]	0.1058
	Severe		1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Nasopharyngitis		11 (12.8%)	7 (15.2%)	18 (13.6%)				
		Mild	10 (11.6%)	6 (13.0%)	16 (12.1%)	0.8768 [0.2987, 2.5738]	0.8908 [0.3475, 2.2832]	-0.0144 [-0.1337, 0.1050]	0.7208
		Moderate	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5452 [0.0320, 9.2814]	0.5452 [0.0296, 10.0406]	-0.0094 [-0.0565, 0.0377]	0.9984
	Pharyngitis	Severe	0 (7.0%)	0 (19.6%)	0 (11.4%)		0.8111 0.6786		
		Mild	6 (7.0%)	9 (19.6%)	15 (11.4%)	0.3124 [0.1034, 0.9440]	0.3620 [0.1378, 0.9514]	-0.1244 [-0.2510, 0.0022]	0.2082
		Moderate	0	0	0				0.9804
		Severe	0	0	0				
	Upper respiratory tract infection		6 (7.0%)	5 (10.9%)	11 (8.3%)				
		Mild	6 (7.0%)	3 (6.5%)	9 (6.8%)	1.0653 [0.2580, 4.3990]	1.0612 [0.2828, 3.9829]	0.0041 [-0.0865, 0.0947]	0.9999

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Upper respiratory tract infection	Moderate	0	2 (4.3%)	2 (1.5%)	0.0962 [0.0045, 2.0636]	0.1030 [0.0051, 2.0861]	-0.0443 [-0.1038, 0.0152]	0.9742
		Severe	0	0	0		0.0460		
	Respiratory tract infection	Mild	5 (5.8%)	3 (6.5%)	8 (6.1%)				
		Moderate	4 (4.7%)	2 (4.3%)	6 (4.5%)	1.1529 [0.2203, 6.0335]	1.1529 [0.2275, 5.8439]	0.0068 [-0.0707, 0.0843]	0.9762
	Pharyngitis streptococcal	Moderate	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5452 [0.0320, 9.2814]	0.5452 [0.0296, 10.0406]	-0.0094 [-0.0565, 0.0377]	0.9729
		Severe	0	0	0		0.6786		
		Mild	3 (3.5%)	3 (6.5%)	6 (4.5%)	1.0159 [0.0887, 11.6304]	1.0154 [0.0955, 10.7928]	0.0003 [-0.0523, 0.0530]	0.9698
		Moderate	2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Moderate	1 (1.2%)	2 (4.3%)	3 (2.3%)	0.2422 [0.0211, 2.7744]	0.2538 [0.0239, 2.6982]	-0.0331 [-0.0964, 0.0303]	0.9975
		Severe	0	0	0		0.2218		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Bronchitis		3 (3.5%)	2 (4.3%)	5 (3.8%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728]	0.0240 [-0.0084, 0.0564]	0.9772
		Moderate	1 (1.2%)	2 (4.3%)	3 (2.3%)	0.2820 [0.0246, 3.2278]	0.2888 0.2985 [0.0303, 2.9359]	-0.0300 [-0.0928, 0.0327]	0.9746
	Respiratory tract infection viral	Severe	0	0	0		0.2763		
			3 (3.5%)	2 (4.3%)	5 (3.8%)				
		Mild	2 (2.3%)	2 (4.3%)	4 (3.0%)	0.5181 [0.0695, 3.8620]	0.5258 [0.0722, 3.8312]	-0.0203 [-0.0870, 0.0464]	0.9986
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	0.5202 1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0		0.4761		
			3 (3.5%)	2 (4.3%)	5 (3.8%)				
	Rhinitis	Mild	3 (3.5%)	2 (4.3%)	5 (3.8%)	0.8474 [0.1314, 5.4642]	0.8547 [0.1417, 5.1551]	-0.0060 [-0.0751, 0.0631]	0.9771
		Moderate	0	0	0		0.8646		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 4 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Ear infection		4 (4.7%)	0	4 (3.0%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9427
		Moderate	3 (3.5%)	0	3 (2.3%)	3.7520 [0.1882, 74.8173]	0.4761 3.6061 [0.1918, 67.8144]	0.0338 [-0.0045, 0.0720]	0.9990
	Gastroenteritis	Severe	0	0	0		0.2124		
		Mild	2 (2.3%)	2 (4.3%)	4 (3.0%)	1.0904 [0.0934, 12.7235]	1.0904 [0.0885, 13.4331]	0.0019 [-0.0504, 0.0542]	0.6918
		Moderate	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.9460 0.1717 [0.0072, 4.1035]	-0.0222 [-0.0647, 0.0204]	0.9804
	Sinusitis	Severe	0	0	0		0.1605		
		Mild	3 (3.5%)	1 (2.2%)	4 (3.0%)	0.5765 [0.0382, 8.6934]	0.5765 [0.0412, 8.0641]	-0.0094 [-0.0585, 0.0397]	0.9747

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 5 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Sinusitis	Moderate	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728]	0.0240 [-0.0084, 0.0564]	0.9772
		Severe	0	0	0		0.2888		
	Enteritis infectious	Mild	1 (1.2%)	2 (4.3%)	3 (2.3%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	1 (1.2%)	0	1 (0.8%)	0.1788 [0.0179, 1.7823]	0.1911 [0.0206, 1.7748]	-0.0428 [-0.1014, 0.0157]	0.9742
	Viral infection	Severe	0	0	0		0.4761		
		Mild	3 (3.5%)	0	3 (2.3%)	2.3046 [0.2460, 21.5915]	2.2307 [0.2550, 19.5124]	0.0353 [-0.0038, 0.0743]	0.9968
		Moderate	3 (3.5%)	0	3 (2.3%)		0.1998		
		Severe	0	0	0				0.9804

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 6 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Gastroenteritis viral		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532] 0.3111	0.0225 [-0.0089, 0.0539]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Helminthic infection		1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624] 0.6234	-0.0109 [-0.0589, 0.0370]	0.9984
		Severe	0	0	0				
	Influenza		1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
Moderate		1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 7 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Otitis media acute		1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.4761 0.1717 [0.0072, 4.1035]	-0.0222 [-0.0647, 0.0204]	0.9804
	Pneumonia	Severe	0	0	0		0.1605		
		Mild	0	2 (4.3%)	2 (1.5%)				
		Moderate	0	2 (4.3%)	2 (1.5%)	0.0962 [0.0045, 2.0636]	0.1030 [0.0051, 2.0861]	-0.0443 [-0.1038, 0.0152]	0.9520
	Tonsillitis	Severe	0	0	0				
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545]	0.0128 [-0.0110, 0.0365]	0.9762
		Severe	0	1 (2.2%)	1 (0.8%)	0.1938 [0.0073, 5.1280]	0.4314 0.2121 [0.0093, 4.8505]	-0.0206 [-0.0618, 0.0205]	0.9804
		Severe	0	0	0		0.2037		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Varicella		2 (2.3%)	0	2 (1.5%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Appendicitis	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Atypical pneumonia		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 9 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Infections and infestations	Conjunctivitis		1 (1.2%)	0	1 (0.8%)					
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
		Moderate	0	0	0				0.9804	
		Severe	0	0	0					
	Conjunctivitis bacterial			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804	
		Moderate	0	0	0					
		Severe	0	0	0					
	Enterobiasis			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9591	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 10 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
Infections and infestations	Laryngitis viral		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1938 [0.0073, 5.1280]	0.2121 [0.0093, 4.8505] 0.2037	-0.0206 [-0.0618, 0.0205]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Molluscum contagiosum		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis externa		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 11 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pulpitis dental		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
	Rotavirus infection	Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9762
	Tinea pedis	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Tooth abscess	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Viral upper respiratory tract infection		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9427
		Moderate	0	0	0				
		Severe	0	0	0				
	Croup infectious			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Cystitis			0	0	0			
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
Eczema infected			0	0	0				
	Mild	0	0	0				0.9804	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 13 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)		OR [95 %-CI] <sup>b</sup>
Infections and infestations	Hordeolum		0	0	0		
		Mild	0	0	0		0.9758
		Moderate	0	0	0		
	Infected bite	Severe	0	0	0		
			0	0	0		
		Mild	0	0	0		0.9804
	Moderate		0	0	0		
		Severe	0	0	0		
			0	0	0		
	Pharyngotonsillitis		0	0	0		
		Mild	0	0	0		0.9758
		Moderate	0	0	0		0.9804
	Severe		0	0	0		
		Urinary tract infection	0	0	0		
		Mild	0	0	0		
Moderate		0	0	0			
	Severe	0	0	0		0.9758	
		0	0	0			
Vulvitis		0	0	0			
	Mild	0	0	0		0.9804	
	Moderate	0	0	0			
Severe		0	0	0			
		0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 14 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders			22 (25.6%)	7 (15.2%)	29 (22.0%)				
		Mild	15 (17.4%)	5 (10.9%)	20 (15.2%)	1.7396 [0.5929, 5.1039]	1.6141 [0.6292, 4.1403] 0.3098	0.0671 [-0.0543, 0.1886]	0.6342
		Moderate	7 (8.1%)	2 (4.3%)	9 (6.8%)	1.9162 [0.3859, 9.5150]	1.8457 [0.4068, 8.3744] 0.4187	0.0375 [-0.0458, 0.1208]	0.9987
		Severe	0	0	0				
	Cough	Mild	7 (8.1%)	4 (8.7%)	11 (8.3%)	1.0653 [0.2580, 4.3990]	1.0612 [0.2828, 3.9829] 0.9300	0.0041 [-0.0865, 0.0947]	0.9673
		Moderate	6 (7.0%)	3 (6.5%)	9 (6.8%)	0.5765 [0.0382, 8.6934]	0.5765 [0.0412, 8.0641] 0.6786	-0.0094 [-0.0585, 0.0397]	0.9984
		Severe	0	0	0				
Respiratory disorder	Mild	2 (2.3%)	2 (4.3%)	4 (3.0%)	0.5765 [0.0382, 8.6934]	0.5765 [0.0412, 8.0641] 0.6786	-0.0094 [-0.0585, 0.0397]	0.9729	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 15 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity				Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984
		Severe	0	0	0		0.6234		
		Asthma	2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5765 [0.0382, 8.6934]	0.5765 [0.0412, 8.0641]	-0.0094 [-0.0585, 0.0397]	0.9984
		Severe	0	0	0		0.6786		
		Epistaxis	3 (3.5%)	0	3 (2.3%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728]	0.0240 [-0.0084, 0.0564]	0.9584
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0		0.4761		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 16 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Sinus congestion		3 (3.5%)	0	3 (2.3%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728]	0.0240 [-0.0084, 0.0564]	0.9772
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
	Wheezing	Severe	0	0	0		0.2888 0.4761		
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
	Nasal congestion	Severe	0	0	0		0.6234 0.4761		
		Mild	2 (2.3%)	0	2 (1.5%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9427

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 17 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0		0.4761		
			1 (1.2%)	1 (2.2%)	2 (1.5%)				
	Rhinitis allergic	Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5452 [0.0320, 9.2814]	0.5452 [0.0296, 10.0406]	-0.0094 [-0.0565, 0.0377]	0.9729
		Moderate	0	0	0		0.6786		
		Severe	0	0	0				
	Rhinorrhoea	Mild	0	2 (4.3%)	2 (1.5%)	0.0962 [0.0045, 2.0636]	0.1030 [0.0051, 2.0861]	-0.0443 [-0.1038, 0.0152]	0.9742
		Moderate	0	0	0		0.0460		
		Severe	0	0	0				
	Allergic cough	Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0		0.4761		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 18 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)		Genotropin n (N=46)		Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value				
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		1 (1.2%)	0	1 (0.8%)					
		Mild	0	0	0					
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
	Laryngospasm	Severe	0	0	0					
		Mild	1 (1.2%)	0	1 (0.8%)					
		Moderate	0	0	0					
	Paranasal sinus discomfort	Severe	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9762	
			Mild	0	0	0				
			Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0					
			Mild	1 (1.2%)	0	1 (0.8%)				
			Moderate	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 19 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				
Gastrointestinal disorders			19 (22.1%)	6 (13.0%)	25 (18.9%)				
		Mild	18 (20.9%)	5 (10.9%)	23 (17.4%)	2.1206 [0.7382, 6.0913]	1.8965 [0.7602, 4.7312] 0.1542	0.0994 [-0.0265, 0.2252]	0.7618
		Moderate	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624] 0.6234	-0.0109 [-0.0589, 0.0370]	0.9747
	Vomiting	Severe	0	0	0				
		Mild	9 (10.5%)	1 (2.2%)	10 (7.6%)	5.1542 [0.6356, 41.7947]	4.7068 [0.6278, 35.2899] 0.0910	0.0822 [0.0048, 0.1596]	0.9687
		Moderate	0	0	0				0.9758
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 20 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Diarrhoea		4 (4.7%)	2 (4.3%)	6 (4.5%)				
		Mild	4 (4.7%)	2 (4.3%)	6 (4.5%)	1.0522 [0.1871, 5.9169]	1.0498 [0.2039, 5.4059]	0.0022 [-0.0722, 0.0766]	0.9932
		Moderate	0	0	0		0.9539		
	Nausea	Severe	0	0	0				
			4 (4.7%)	1 (2.2%)	5 (3.8%)				
		Mild	3 (3.5%)	0	3 (2.3%)	3.7520 [0.1882, 74.8173]	3.6061 [0.1918, 67.8144]	0.0338 [-0.0045, 0.0720]	0.9553
	Abdominal pain	Moderate	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984
		Severe	0	0	0		0.6234		
			2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9729
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0		0.4761		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Constipation		3 (3.5%)	0	3 (2.3%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728] 0.2888	0.0240 [-0.0084, 0.0564]	0.9772
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Abdominal pain upper	Severe	0	0	0				
		Mild	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532] 0.3111	0.0225 [-0.0089, 0.0539]	0.9732
		Moderate	0	0	0				
	Dyspepsia	Severe	0	0	0				
		Mild	2 (2.3%)	0	2 (1.5%)	3.4615 [0.1537, 77.9731]	3.1818 [0.1646, 61.4950] 0.2585	0.0256 [-0.0078, 0.0589]	0.9772
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 22 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Toothache		1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624] 0.6234	-0.0109 [-0.0589, 0.0370]	0.9984
		Moderate	0	0	0				
	Abdominal discomfort	Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9974
	Aphthous ulcer	Moderate	0	0	0				
		Severe	0	0	0				
			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Gastric disorder		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal motility disorder		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				
	Lip swelling		0	0	0				
		Mild	0	0	0				0.9804
Moderate		0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 24 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>					Subgroup Interaction p-value	
			TransCon hGH (N=86)	Genotropin (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>		RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions			15 (17.4%)	6 (13.0%)	21 (15.9%)				
		Mild	11 (12.8%)	4 (8.7%)	15 (11.4%)	1.5226 [0.4553, 5.0917]	1.4556 [0.4899, 4.3243]	0.0397 [-0.0680, 0.1474]	0.2603
		Moderate	4 (4.7%)	2 (4.3%)	6 (4.5%)	1.0164 [0.1763, 5.8581]	1.0154 [0.1960, 5.2600]	0.0007 [-0.0726, 0.0740]	0.9998
		Severe	0	0	0		0.4958		
		Pyrexia	13 (15.1%)	3 (6.5%)	16 (12.1%)		1.5823 [0.4441, 5.6371]	0.0378 [-0.0583, 0.1340]	0.5119
		Mild	9 (10.5%)	3 (6.5%)	12 (9.1%)	1.6463 [0.4219, 6.4240]	1.5823 [0.4441, 5.6371]	0.0378 [-0.0583, 0.1340]	0.5119
		Moderate	4 (4.7%)	0	4 (3.0%)	4.9024 [0.2561, 93.8438]	4.6364 [0.2571, 83.6154]	0.0450 [0.0011, 0.0890]	0.9785
		Severe	0	0	0		0.4726		
		Fatigue	1 (1.2%)	1 (2.2%)	2 (1.5%)		0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984
	Moderate	0	0	0		0.6234			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and administration site conditions	Face oedema		0	1 (2.2%)	1 (0.8%)				
		Mild	0	0	0				
		Moderate	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035]	-0.0222 [-0.0647, 0.0204]	0.9804
	Gait disturbance	Severe	0	0	0				
		Mild	1 (1.2%)	0	1 (0.8%)				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545]	0.0128 [-0.0110, 0.0365]	0.9762
	Influenza like illness	Severe	0	0	0				
		Mild	0	1 (2.2%)	1 (0.8%)				
		Moderate	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035]	-0.0222 [-0.0647, 0.0204]	0.9804
		Severe	0	0	0		0.1605		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 26 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and administration site conditions	Injection site atrophy		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
	Injection site swelling	Severe	0	0	0				
			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
	Injection site urticaria	Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 27 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value	
			TransCon hGH (N=86)	Genotropin (N=46)	Total (N=132)					
General disorders and administrative site conditions	Medical device administration site		0	0	0					
		Mild	0	0	0				0.9758	
		Moderate	0	0	0					
	Vaccination site pain	Severe	0	0	0					
		Mild	0	0	0				0.9758	
		Moderate	0	0	0					
	Nervous system disorders			13 (15.1%)	7 (15.2%)	20 (15.2%)				
		Mild	9 (10.5%)	4 (8.7%)	13 (9.8%)	1.1652 [0.3304, 4.1088]	1.1423 [0.3799, 3.4343]	0.0126 [-0.0894, 0.1147]	0.2358	
		Moderate	4 (4.7%)	3 (6.5%)	7 (5.3%)	0.6557 [0.1379, 3.1188]	0.6769 [0.1608, 2.8489]	-0.0215 [-0.1050, 0.0620]	0.9994	
Severe		0	0	0		0.5955				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 28 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Nervous system disorders	Headache		12 (14.0%)	6 (13.0%)	18 (13.6%)				
		Mild	8 (9.3%)	3 (6.5%)	11 (8.3%)	1.4035 [0.3466, 5.6836]	1.3538 [0.3844, 4.7683]	0.0235 [-0.0691, 0.1162]	0.5085
		Moderate	4 (4.7%)	3 (6.5%)	7 (5.3%)	0.6557 [0.1379, 3.1188]	0.6353 0.6769 [0.1608, 2.8489]	-0.0215 [-0.1050, 0.0620]	0.9994
	Dizziness	Severe	0	0	0		0.5955		
		Mild	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532]	0.0225 [-0.0089, 0.0539]	0.9584
		Moderate	2 (2.3%)	0	2 (1.5%)		0.3111		
	Post-traumatic headache	Severe	0	0	0				
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984
		Moderate	1 (1.2%)	1 (2.2%)	2 (1.5%)		0.6234		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Nervous system disorders	Migraine		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
		Moderate	0	0	0				
	Tremor	Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
Injury, poisoning and procedural complications			11 (12.8%)	5 (10.9%)	16 (12.1%)				
	Mild	7 (8.1%)	4 (8.7%)	11 (8.3%)	0.8961 [0.2468, 3.2528]	0.9057 [0.2845, 2.8828] 0.8678	-0.0084 [-0.1080, 0.0913]	0.9288	
	Moderate	4 (4.7%)	1 (2.2%)	5 (3.8%)	2.1528 [0.2361, 19.6316]	2.0995 [0.2475, 17.8071] 0.4872	0.0244 [-0.0373, 0.0860]	0.9791	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Animal bite		1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624] 0.6234	-0.0109 [-0.0589, 0.0370]	0.9984
		Moderate	0	0	0				
	Ankle fracture	Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
	Arthropod bite	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				
			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9557
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 31 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Injury, poisoning and procedural complications	Burns first degree		0	1 (2.2%)	1 (0.8%)					
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804	
		Moderate	0	0	0					
	Burns second degree	Severe	0	0	0					
			1 (1.2%)	0	1 (0.8%)					
		Mild	0	0	0					
	Concussion	Moderate		1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9762
			Severe	0	0	0				
		Mild		0	1 (2.2%)	1 (0.8%)				
				0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 32 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Contusion		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9762
		Moderate	0	0	0				0.9804
	Face injury	Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
	Fall	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9762
	Head injury	Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 33 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Laceration		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
	Ligament sprain	Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Meniscus injury	Moderate	0	0	0				
		Severe	0	0	0				
			0	1 (2.2%)	1 (0.8%)				
	Muscle strain	Mild	0	0	0				
		Moderate	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
		Severe	0	0	0				
		1 (1.2%)	0	1 (0.8%)					
		Mild	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 34 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Muscle strain	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				
	Post-traumatic pain	Moderate	1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9427
	Radius fracture	Moderate	0	0	0				
		Severe	0	0	0				
	Wrist fracture	Moderate	1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 35 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin (N=46)	Total (N=132)				
Injury, poisoning and procedural complications	Thermal burn		0	0	0				
		Mild	0	0	0				0.9758
		Moderate	0	0	0				
	Upper limb fracture	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Musculoskeletal and connective tissue disorders			9 (10.5%)	5 (10.9%)	14 (10.6%)			
Mild		7 (8.1%)	5 (10.9%)	12 (9.1%)	0.7243 [0.2158, 2.4309]	0.7450 [0.2460, 2.2559]	-0.0275 [-0.1344, 0.0794]	0.8148	
Moderate		2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532]	0.0225 [-0.0089, 0.0539]	0.9772	
Severe		0	0	0		0.3111			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Arthralgia		5 (5.8%)	1 (2.2%)	6 (4.5%)				
		Mild	5 (5.8%)	1 (2.2%)	6 (4.5%)	2.7126 [0.3089, 23.8221]	2.6072 [0.3205, 21.2120] 0.3511	0.0356 [-0.0295, 0.1008]	0.9973
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain in extremity		3 (3.5%)	3 (6.5%)	6 (4.5%)				
		Mild	2 (2.3%)	3 (6.5%)	5 (3.8%)	0.3324 [0.0527, 2.0976]	0.3464 [0.0580, 2.0690] 0.2261	-0.0425 [-0.1204, 0.0355]	0.8265
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Musculoskeletal pain	Severe	0	0	0				
			2 (2.3%)	0	2 (1.5%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 37 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0		0.4761		
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
	Arthritis reactive	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
	Back pain	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				
		Mild	0	0	0				
	Neck mass	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 38 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=86) Genotropin n (N=46) Total (N=132)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction n p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Musculoskeletal and connective tissue disorders	Neck pain		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9427
		Moderate	0	0	0				
	Pain in jaw	Severe	0	0	0				
			1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
	Synovial cyst	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				
			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1938 [0.0073, 5.1280]	0.2121 [0.0093, 4.8505] 0.2037	-0.0206 [-0.0618, 0.0205]	0.9804
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 39 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders			6 (7.0%)	6 (13.0%)	12 (9.1%)				
		Mild	4 (4.7%)	6 (13.0%)	10 (7.6%)	0.3226 [0.0864, 1.2046]	0.3540 [0.1059, 1.1832]	-0.0849 [-0.1923, 0.0224]	0.9757
		Moderate	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532]	0.0225 [-0.0089, 0.0539]	0.9772
		Severe	0	0	0		0.3111		
		Secondary hypothyroidism	4 (4.7%)	3 (6.5%)	7 (5.3%)				
		Mild	3 (3.5%)	3 (6.5%)	6 (4.5%)	0.5259 [0.1017, 2.7203]	0.5431 [0.1145, 2.5767]	-0.0297 [-0.1109, 0.0515]	0.9691
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0		0.4761		
		Diabetes insipidus	1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984
		Moderate	0	0	0		0.6234		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 40 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Adrenal insufficiency		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Hypothyroidism	Severe	0	0	0				
			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
	Secondary adrenocortical insufficiency	Moderate	0	0	0				
		Severe	0	0	0				
			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9557
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 41 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders			6 (7.0%)	4 (8.7%)	10 (7.6%)				
		Mild	5 (5.8%)	2 (4.3%)	7 (5.3%)	1.3704 [0.2531, 7.4208]	1.3500 [0.2664, 6.8421] 0.7169	0.0150 [-0.0617, 0.0917]	0.9702
		Moderate	1 (1.2%)	2 (4.3%)	3 (2.3%)	0.2422 [0.0211, 2.7744]	0.2538 [0.0239, 2.6982] 0.2218	-0.0331 [-0.0964, 0.0303]	0.9975
		Severe	0	0	0				
		Rash	3 (3.5%)	1 (2.2%)	4 (3.0%)				
		Mild	3 (3.5%)	1 (2.2%)	4 (3.0%)	1.6106 [0.1660, 15.6230]	1.5919 [0.1756, 14.4286] 0.6777	0.0131 [-0.0448, 0.0710]	0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
		Urticaria	1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 42 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Dermatitis allergic		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1938 [0.0073, 5.1280]	0.2121 [0.0093, 4.8505] 0.2037	-0.0206 [-0.0618, 0.0205]	0.9804
		Moderate	0	0	0				
	Eczema	Severe	0	0	0				
		Mild	1 (1.2%)	0	1 (0.8%)				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	Rash erythematous	Severe	0	0	0				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
	Rash pruritic	Severe	0	0	0				
		Mild	0	1 (2.2%)	1 (0.8%)				
		Moderate	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 43 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035]	-0.0222 [-0.0647, 0.0204]	0.9804
		Severe	0	0	0	0.1605			
		Cafe au lait spots	0	0	0				
	Dermatitis contact	Mild	0	0	0			0.9804	
		Moderate	0	0	0				
		Severe	0	0	0				
	Keratosis pilaris	Mild	0	0	0			0.9804	
		Moderate	0	0	0				
		Severe	0	0	0				
	Petechiae	Mild	0	0	0			0.9804	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 44 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Pityriasis alba		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
Blood and lymphatic system disorders	Iron deficiency anaemia		7 (8.1%)	2 (4.3%)	9 (6.8%)				
		Mild	5 (5.8%)	2 (4.3%)	7 (5.3%)	1.3544 [0.2584, 7.0975]	1.3380 [0.2759, 6.4884] 0.7169	0.0150 [-0.0632, 0.0932]	0.9995
		Moderate	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728] 0.2888	0.0240 [-0.0084, 0.0564]	0.9772
		Severe	0	0	0				
		Mild	3 (3.5%)	0	3 (2.3%)				
	Mild	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728] 0.2888	0.0240 [-0.0084, 0.0564]	0.9772	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 45 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545]	0.0128 [-0.0110, 0.0365]	0.9762
		Severe	0	0	0		0.4314		
		Anaemia	1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5765 [0.0382, 8.6934]	0.5765 [0.0412, 8.0641]	-0.0094 [-0.0585, 0.0397]	0.9984
		Moderate	0	0	0		0.6786		
		Severe	0	0	0				
		Lymphadenopathy	1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035]	-0.0222 [-0.0647, 0.0204]	0.9804
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0		0.4761		
		Neutropenia	2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532]	0.0225 [-0.0089, 0.0539]	0.9772
	Moderate	0	0	0		0.3111			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Immune system disorders				6 (7.0%)	2 (4.3%)	8 (6.1%)					
			Mild	5 (5.8%)	2 (4.3%)	7 (5.3%)	1.2917 [0.2369, 7.0434]	1.2692 [0.2600, 6.1955] 0.7681	0.0119 [-0.0643, 0.0881]	0.9755	
			Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
			Severe	0	0	0					
			Seasonal allergy	Mild	3 (3.5%)	1 (2.2%)	4 (3.0%)				
				Mild	3 (3.5%)	1 (2.2%)	4 (3.0%)	1.5484 [0.1548, 15.4908]	1.5231 [0.1647, 14.0805] 0.7092	0.0116 [-0.0453, 0.0685]	0.9800
				Moderate	0	0	0				
			Allergy to animal	Severe	0	0	0				
				Mild	2 (2.3%)	0	2 (1.5%)				
				Mild	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532] 0.3111	0.0225 [-0.0089, 0.0539]	0.9772
					Moderate	0	0	0			
					Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 47 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Immune system disorders	Hypersensitivity		1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035]	-0.0222 [-0.0647, 0.0204]	0.9804
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
	Severe	0	0	0		0.4761			
Eye disorders	Strabismus		5 (5.8%)	2 (4.3%)	7 (5.3%)				
		Mild	5 (5.8%)	2 (4.3%)	7 (5.3%)	1.2917 [0.2369, 7.0434]	1.2692 [0.2600, 6.1955]	0.0119 [-0.0643, 0.0881]	0.9755
		Moderate	0	0	0		0.7681		
	Severe	0	0	0					
	Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)					
	Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0303, 8.2561]	0.5077 [0.0328, 7.8624]	-0.0109 [-0.0589, 0.0370]	0.9984	
	Moderate	0	0	0		0.6234			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 48 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Eye disorders	Astigmatism			1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
		Moderate	0	0	0					
		Severe	0	0	0					
		Conjunctivitis allergic		1 (1.2%)	0	1 (0.8%)				
			Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0					
		Severe	0	0	0					
	Eye haemorrhage		1 (1.2%)	0	1 (0.8%)					
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
		Moderate	0	0	0					
		Severe	0	0	0					
Hypermetropia			1 (1.2%)	0	1 (0.8%)					
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
	Moderate	0	0	0						
	Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 49 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Eye disorders	Myopia		0	1 (2.2%)	1 (0.8%)					
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804	
		Moderate	0	0	0					
	Eye swelling	Severe	0	0	0					
			0	0	0					
		Mild	0	0	0				0.9804	
		Moderate	0	0	0					
	Investigations	Insulin-like growth factor increased	Severe	0	0	0				
				0	0	0				
			Mild	2 (2.3%)	0	2 (1.5%)				
Investigations		Mild	5 (5.8%)	2 (4.3%)	7 (5.3%)	1.3544 [0.2584, 7.0975]	1.3380 [0.2759, 6.4884] 0.7169	0.0150 [-0.0632, 0.0932]	0.8847	
		Moderate	0	0	0					
		Severe	0	0	0					
			2 (2.3%)	0	2 (1.5%)					
Investigations		Mild	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728] 0.2888	0.0240 [-0.0084, 0.0564]	0.9772	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 50 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Blood iron decreased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood iron increased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood thyroid stimulating hormone increased		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 51 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Eosinophils count increased		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9974
		Moderate	0	0	0				
		Severe	0	0	0				
	Thyroxine decreased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Transaminases increased		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 52 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>				Subgroup Interaction p-value	
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>		RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>
Investigations	Alanine aminotransferase increased		0	0	0			
		Mild	0	0	0			0.9758
		Moderate	0	0	0			
	Aspartate aminotransferase increased	Severe	0	0	0			
		Mild	0	0	0			0.9758
		Moderate	0	0	0			
	Blood cortisol decreased	Severe	0	0	0			
		Mild	0	0	0			0.9804
		Moderate	0	0	0			
	Cortisol free urine decreased	Severe	0	0	0			
		Mild	0	0	0			0.9804
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 53 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	White blood cell count decreased		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
Psychiatric disorders	4 (4.7%)	1 (2.2%)	5 (3.8%)						
Psychiatric disorders	Attention deficit/hyperactivity disorder	Mild	3 (3.5%)	1 (2.2%)	4 (3.0%)	1.6710 [0.1786, 15.6358]	1.6606 [0.1866, 14.7795]	0.0146 [-0.0442, 0.0735]	0.9990
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317]	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0		0.6442	0.4761	
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.2%)	2 (1.5%)	0.5765 [0.0382, 8.6934]	0.5765 [0.0412, 8.0641]	-0.0094 [-0.0585, 0.0397]	0.9984
		Moderate	0	0	0		0.6786		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 54 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Psychiatric disorders	Affect lability		1 (1.2%)	0	1 (0.8%)					
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
		Moderate	0	0	0					
	Depressive symptom	Severe	0	0	0					
			1 (1.2%)	0	1 (0.8%)					
		Mild	0	0	0					
	Enuresis	Moderate		1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
			Mild	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9762
			Severe	0	0	0				
		Severe		0	0	0				
			Mild	1 (1.2%)	0	1 (0.8%)				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 55 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity				Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Cardiac disorders			2 (2.3%)	0	2 (1.5%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Severe	0	0	0				
		Sinoatrial block	1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				
		Sinus tachycardia	1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
	Moderate	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 56 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Cardiac disorders	Tachycardia		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				
Ear and labyrinth disorders			2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532] 0.3111	0.0225 [-0.0089, 0.0539]	0.9962
		Moderate	0	0	0				
	Ear pain	Severe	0	0	0				
		Mild	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532] 0.3111	0.0225 [-0.0089, 0.0539]	0.9962
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 57 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=86)		Genotropin n (N=46)		Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			2 (2.3%)	0	2 (1.5%)					
		Mild	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728] 0.2888	0.0240 [-0.0084, 0.0564]	0.9732	
		Moderate	0	0	0					
		Severe	0	0	0					
		Osteoma								
		Mild	1 (1.2%)	0	1 (0.8%)	1.9756 [0.0748, 52.1634]	1.9091 [0.0835, 43.6545] 0.4314	0.0128 [-0.0110, 0.0365]	0.9762	
		Moderate	0	0	0					
		Severe	0	0	0					
		Skin papilloma								
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9769	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 58 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Renal and urinary disorders			2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.6378 [0.1231, 56.5438]	2.5758 [0.1272, 52.1532] 0.3111	0.0225 [-0.0089, 0.0539]	0.9772
		Moderate	0	0	0				
		Severe	0	0	0				
		Pollakiuria							
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				
		Polyuria							
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 59 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Reproductive system and breast disorders			0	2 (4.3%)	2 (1.5%)				
		Mild	0	2 (4.3%)	2 (1.5%)	0.1788 [0.0179, 1.7823]	0.1911 [0.0206, 1.7748] 0.0588	-0.0428 [-0.1014, 0.0157]	0.9742
		Moderate	0	0	0				
		Severe	0	0	0				
		Penile adhesion		0	2 (4.3%)	2 (1.5%)			
		Mild	0	2 (4.3%)	2 (1.5%)	0.1788 [0.0179, 1.7823]	0.1911 [0.0206, 1.7748] 0.0588	-0.0428 [-0.1014, 0.0157]	0.9742
		Moderate	0	0	0				
		Severe	0	0	0				
		Genital discomfort		0	1 (2.2%)	1 (0.8%)			
	Mild	0	1 (2.2%)	1 (0.8%)	0.1938 [0.0073, 5.1280]	0.2121 [0.0093, 4.8505] 0.2037	-0.0206 [-0.0618, 0.0205]	0.9804	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 60 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Hepatobiliary disorders			0	1 (2.2%)	1 (0.8%)					
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804	
		Moderate	0	0	0					
		Severe	0	0	0					
		Hepatomegaly								
		Mild	0	1 (2.2%)	1 (0.8%)	0.1654 [0.0066, 4.1732]	0.1717 [0.0072, 4.1035] 0.1605	-0.0222 [-0.0647, 0.0204]	0.9804	
		Moderate	0	0	0					
		Severe	0	0	0					
	Metabolism and nutrition disorders			1 (1.2%)	0	1 (0.8%)				
			Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 61 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Male

System Organ Class	Organ Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=86)	Genotropin n (N=46)	Total (N=132)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Metabolism and nutrition disorders	Polydipsia		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
		Moderate	0	0	0				
		Severe	0	0	0				
Vascular disorders	Hypotension		0	0	0				
		Mild	0	0	0				0.9722
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	0	0	0				0.9722
		Moderate	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 62 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR	RD
							[95 %-CI] <sup>b</sup>	p-value <sup>c</sup>
Any adverse event			16 (84.2%)	6 (60.0%)	22 (75.9%)			
	Mild		10 (52.6%)	4 (40.0%)	14 (48.3%)	2.0750 [0.4015, 10.7248]	1.4300 [0.6072, 3.3676] 0.3979	0.1673 [-0.1965, 0.5312]
	Moderate		6 (31.6%)	2 (20.0%)	8 (27.6%)	1.5534 [0.2260, 10.6759]	1.3333 [0.3855, 4.6114] 0.6656	0.0739 [-0.2394, 0.3872]
Infections and infestations			12 (63.2%)	5 (50.0%)	17 (58.6%)			
	Mild		7 (36.8%)	4 (40.0%)	11 (37.9%)	0.9667 [0.1927, 4.8496]	0.9800 [0.3711, 2.5881] 0.9683	-0.0078 [-0.3785, 0.3630]
	Moderate		5 (26.3%)	1 (10.0%)	6 (20.7%)	2.8125 [0.2066, 38.2949]	1.9063 [0.3965, 9.1655] 0.4401	0.1128 [-0.1372, 0.3628]
Pharyngitis	Severe		0	0	0			
	Mild		4 (21.1%)	1 (10.0%)	5 (17.2%)	1.6000 [0.1385, 18.4900]	1.5200 [0.1608, 14.3657] 0.7167	0.0506 [-0.1972, 0.2984]

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 63 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Pharyngitis	Moderate	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451]	0.0311 [-0.0492, 0.1115]
		Severe	0	0	0		0.6171	
	Viral infection	Mild	3 (15.8%)	0	3 (10.3%)	1.6308 [0.1376, 19.3313]	1.4603 [0.1867, 11.4240]	0.0895 [-0.0424, 0.2214]
		Moderate	2 (10.5%)	0	2 (6.9%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0584 [-0.0492, 0.1659]
	Ear infection	Severe	0	0	0		0.4386	
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318]	-0.0973 [-0.2819, 0.0873]
	Enterobiasis	Moderate	0	1 (10.0%)	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451]	0.0311 [-0.0492, 0.1115]
		Severe	0	0	0		0.6171	
		Mild	2 (10.5%)	0	2 (6.9%)	3.5185 [0.1511, 81.9250]	3.1250 [0.1666, 58.6274]	0.1167 [-0.0302, 0.2637]
		Moderate	2 (10.5%)	0	2 (6.9%)		0.2627	
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 64 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Gastroenteritis		1 (5.3%)	1 (10.0%)	2 (6.9%)			
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0389 [-0.2514, 0.1736]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasopharyngitis		1 (5.3%)	1 (10.0%)	2 (6.9%)			
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.3200 [0.0117, 8.7358]	0.3200 [0.0098, 10.4012] 0.4986	-0.0661 [-0.2712, 0.1389]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngotonsillitis		1 (5.3%)	1 (10.0%)	2 (6.9%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 65 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Respiratory tract infection		2 (10.5%)	0	2 (6.9%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
	Bronchitis	Severe	0	0	0			
		Mild	0	1 (10.0%)	1 (3.4%)			
		Moderate	0	1 (10.0%)	1 (3.4%)	0.0370 [0.0005, 2.8230]	0.1333 [0.0085, 2.0828] 0.0455	-0.1245 [-0.3263, 0.0773]
	Conjunctivitis	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 66 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Croup infectious		0	1 (10.0%)	1 (3.4%)			
		Mild	0	1 (10.0%)	1 (3.4%)			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cystitis		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eczema infected		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastroenteritis viral		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 67 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Hordeolum		0	1 (10.0%)	1 (3.4%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
	Infected bite	Severe	0	0	0			
			1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
	Pharyngitis streptococcal	Moderate	0	0	0			
		Severe	0	0	0			
			0	1 (10.0%)	1 (3.4%)			
	Pneumonia	Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
		Severe	0	0	0			
			1 (5.3%)	0	1 (3.4%)			
		Mild	0	0	0			
Moderate		1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]	
Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 68 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Rhinitis		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
	Sinusitis	Severe	0	0	0			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
	Urinary tract infection	Severe	0	0	0			
		Mild	0	1 (10.0%)	1 (3.4%)	0.0370 [0.0005, 2.8230]	0.1333 [0.0085, 2.0828] 0.0455	-0.1245 [-0.3263, 0.0773]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 69 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Viral upper respiratory tract infection		0	1 (10.0%)	1 (3.4%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
	Vulvitis	Severe	0	0	0			
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Moderate	1 (5.3%)	0	1 (3.4%)			
	Appendicitis	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Atypical pneumonia	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 70 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Conjunctivitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Enteritis infectious	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Helminthic infection	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Influenza	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Laryngitis viral	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 71 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
			(N=19)	(N=10)	(N=29)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>	
Infections and infestations	Molluscum contagiosum		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis externa			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
				0	0	0			
				0	0	0			
	Otitis media acute			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Pulpitis dental			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 72 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Respiratory tract infection viral	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rotavirus infection	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tinea pedis	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tonsillitis	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tooth abscess	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 73 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Upper respiratory tract infection		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Varicella		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Gastrointestinal disorders			5 (26.3%)	2 (20.0%)	7 (24.1%)			
			Mild	5 (26.3%)	1 (10.0%)	6 (20.7%)	3.3455 [0.3218, 34.7749]	2.7200 [0.3493, 21.1818]	0.1673 [-0.1060, 0.4406]
			Moderate	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318]	-0.0973 [-0.2819, 0.0873]
Diarrhoea			0	0	0				
		Mild	2 (10.5%)	1 (10.0%)	3 (10.3%)	1.2308 [0.0954, 15.8721]	1.2000 [0.1260, 11.4277]	0.0195 [-0.2145, 0.2534]	
		Moderate	0	0	0				
			0	0	0				
			0	0	0				
			0	0	0				
		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 74 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Abdominal pain upper		1 (5.3%)	1 (10.0%)	2 (6.9%)			
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0389 [-0.2514, 0.1736]
		Moderate	0	0	0			
	Vomiting	Severe	0	0	0			
			0	2 (20.0%)	2 (6.9%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
	Abdominal discomfort	Moderate	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Severe	0	0	0			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 75 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Abdominal pain	Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
		Severe	0	0	0			
	Lip swelling	Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nausea	Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
		Severe	0	0	0			
	Aphthous ulcer	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 76 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Constipation		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Dyspepsia	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Gastric disorder	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Gastrointestinal motility disorder	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Toothache		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 77 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions			3 (15.8%)	3 (30.0%)	6 (20.7%)			
		Mild	3 (15.8%)	3 (30.0%)	6 (20.7%)	0.4308 [0.0675, 2.7489]	0.5067 [0.1100, 2.3340] 0.3838	-0.1440 [-0.4748, 0.1868]
		Moderate	0	0	0			
		Severe	0	0	0			
		Pyrexia						
		Mild	3 (15.8%)	2 (20.0%)	5 (17.2%)	0.7231 [0.0964, 5.4227]	0.7600 [0.1340, 4.3096] 0.7613	-0.0467 [-0.3449, 0.2516]
		Moderate	0	0	0			
		Severe	0	0	0			
		Medical device discomfort						
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 78 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR	RD
							[95 %-CI] <sup>b</sup>	p-value <sup>c</sup>
General disorders and site administration site conditions	Vaccination		0	1 (10.0%)	1 (3.4%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
	Face oedema	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Fatigue	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Gait disturbance	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 79 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=10)	(N=29)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
General disorders and like illness administration site conditions	Influenza		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Injection site atrophy	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Injection site swelling	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Injection site urticaria	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 80 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>							
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders			5 (26.3%)	1 (10.0%)	6 (20.7%)				
		Mild	5 (26.3%)	1 (10.0%)	6 (20.7%)	3.3455 [0.3218, 34.7749]	2.7200 [0.3493, 21.1818] 0.3115	0.1673 [-0.1060, 0.4406]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Cough		3 (15.8%)	0	3 (10.3%)			
		Mild	3 (15.8%)	0	3 (10.3%)	2.3143 [0.2089, 25.6453]	1.8777 [0.2528, 13.9466] 0.2232	0.1479 [-0.0159, 0.3116]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Epistaxis		0	1 (10.0%)	1 (3.4%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal congestion		0	1 (10.0%)	1 (3.4%)				
	Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]		
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 81 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
	Rhinitis allergic	Severe	0	0	0			
			1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
	Allergic cough	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Asthma	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 82 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=10)	(N=29)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Laryngospasm	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Paranasal sinus discomfort	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Rhinorrhoea	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinus congestion		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 83 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Wheezing	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
Injury, poisoning and procedural complications	Severe	0	0	0				
		3 (15.8%)	1 (10.0%)	4 (13.8%)				
	Mild	2 (10.5%)	1 (10.0%)	3 (10.3%)	1.2308 [0.0954, 15.8721]	1.2000 [0.1260, 11.4277]	0.0195 [-0.2145, 0.2534]	
	Moderate	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0584 [-0.0492, 0.1659]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 84 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and bite procedural complications	Arthropod		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
	Contusion	Severe	0	0	0			
			1 (5.3%)	0	1 (3.4%)			
		Mild	0	0	0			
		Moderate	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Severe	0	0	0			
		Post-traumatic pain	0	1 (10.0%)	1 (3.4%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
		Severe	0	0	0			
Thermal burn		0	1 (10.0%)	1 (3.4%)				
	Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 85 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and fracture procedural complications	Upper limb fracture		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
	Animal bite	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Ankle fracture	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Burns first degree	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 86 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=10)	(N=29)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Burns second degree		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Concussion	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Face injury	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Fall	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Head injury	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 87 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>
							[95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Laceration		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Ligament sprain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Meniscus injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Muscle strain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Radius fracture		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 88 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and fracture procedural complications	Wrist		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Investigations	Alanine aminotransferase increased		3 (15.8%)	1 (10.0%)	4 (13.8%)			
		Mild	3 (15.8%)	1 (10.0%)	4 (13.8%)	2.0000 [0.1754, 22.7989]	1.8000 [0.2189, 14.8009] 0.5797	0.0778 [-0.1727, 0.3283]
		Moderate	0	0	0			
		Severe	0	0	0			
	Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 89 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Aspartate aminotransferase increased		0	1 (10.0%)	1 (3.4%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood cortisol decreased		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cortisol free urine decreased		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 90 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Eosinophils count increased		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
	White blood cell count decreased	Severe	0	0	0			
			1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
	Blood iron decreased	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 91 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>
							[95 %-CI] <sup>b</sup>	
Investigations	Blood iron increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood thyroid stimulating hormone increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Insulin-like growth factor increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroxine decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 92 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>								
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Investigations	Transaminases increased		0	0	0					
		Mild	0	0	0					
		Moderate	0	0	0					
		Severe	0	0	0					
	Endocrine disorders			3 (15.8%)	0	3 (10.3%)				
		Mild		3 (15.8%)	0	3 (10.3%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826] 0.1603	0.1751 [0.0016, 0.3486]	
		Moderate		0	0	0				
		Severe		0	0	0				
		Secondary hypothyroidism			3 (15.8%)	0	3 (10.3%)			
			Mild		3 (15.8%)	0	3 (10.3%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826] 0.1603	0.1751 [0.0016, 0.3486]
			0	0	0					
			0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 93 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Secondary adrenocortical insufficiency		1 (5.3%)	0	1 (3.4%)				
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Adrenal insufficiency		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Diabetes insipidus		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Hypothyroidism		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
				Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 94 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders			1 (5.3%)	2 (20.0%)	3 (10.3%)			
		Mild	1 (5.3%)	2 (20.0%)	3 (10.3%)	0.1600 [0.0084, 3.0313]	0.1600 [0.0071, 3.5811] 0.1782	-0.1634 [-0.4290, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
		Headache						
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.3200 [0.0117, 8.7358]	0.3200 [0.0098, 10.4012] 0.4986	-0.0661 [-0.2712, 0.1389]
		Moderate	0	0	0			
		Severe	0	0	0			
		Dizziness						
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0			
		Severe	0	0	0			
	Migraine							
	Mild	0	0	0				
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders	Post-traumatic headache		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tremor	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
Skin and subcutaneous tissue disorders			3 (15.8%)	0	3 (10.3%)			
	Mild	3 (15.8%)	0	3 (10.3%)	2.3779 [0.2054, 27.5300]	1.9485 [0.2711, 14.0035] 0.2605	0.1206 [-0.0310, 0.2723]	
	Moderate	0	0	0				
	Severe	0	0	0				
	Cafe au lait spots		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 96 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Dermatitis contact		1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Moderate	0	0	0			
	Keratosis pilaris	Severe	0	0	0			
			1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
	Petechiae	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 97 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=29)		[95 %-CI] <sup>b</sup>
			(N=19)	(N=10)		[95 %-CI] <sup>b</sup>			
Skin and subcutaneous tissue disorders	Pityriasis alba		1 (5.3%)	0	1 (3.4%)				
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857	1.2000	0.0311	
						[0.0309, 53.5122]	[0.0768, 18.7451]	[-0.0492, 0.1115]	
		Moderate	0	0	0		0.6171		
		Severe	0	0	0				
	Dermatitis allergic			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Eczema			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Rash			0	0	0			
		Mild	0	0	0				
Moderate		0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 98 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Rash erythematous		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Rash pruritic	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Urticaria	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Ear and labyrinth disorders	Severe	0	0	0			
			2 (10.5%)	0	2 (6.9%)			
		Mild	2 (10.5%)	0	2 (6.9%)	1.6308 [0.1376, 19.3313]	1.4603 [0.1867, 11.4240]	0.0895 [-0.0424, 0.2214]
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 99 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Ear and labyrinth disorders	Ear pain		2 (10.5%)	0	2 (6.9%)			
		Mild	2 (10.5%)	0	2 (6.9%)	1.6308 [0.1376, 19.3313]	1.4603 [0.1867, 11.4240] 0.3599	0.0895 [-0.0424, 0.2214]
		Moderate	0	0	0			
		Severe	0	0	0			
Musculoskeletal and connective tissue disorders	Pain in extremity		1 (5.3%)	1 (10.0%)	2 (6.9%)			
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0389 [-0.2514, 0.1736]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0389 [-0.2514, 0.1736]
		Moderate	0	0	0			
Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Neck pain		0	1 (10.0%)	1 (3.4%)			
		Mild	0	1 (10.0%)	1 (3.4%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318]	-0.0973 [-0.2819, 0.0873]
		Moderate	0	0	0		0.1967	
	Arthralgia	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Arthritis reactive	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Back pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 101 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Neck mass	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain in jaw	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Synovial cyst	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 102 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			1 (5.3%)	1 (10.0%)	2 (6.9%)			
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0389 [-0.2514, 0.1736]
		Moderate	0	0	0			
		Severe	0	0	0			
		Skin papilloma	1 (5.3%)	1 (10.0%)	2 (6.9%)			
		Mild	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0389 [-0.2514, 0.1736]
		Moderate	0	0	0			
		Severe	0	0	0			
		Osteoma	0	0	0			
		Mild	0	0	0			
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Vascular disorders	Hypotension		2 (10.5%)	0	2 (6.9%)			
		Mild	2 (10.5%)	0	2 (6.9%)	3.5185 [0.1511, 81.9250]	3.1250 [0.1666, 58.6274] 0.2627	0.1167 [-0.0302, 0.2637]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	2 (10.5%)	0	2 (6.9%)	3.5185 [0.1511, 81.9250]	3.1250 [0.1666, 58.6274] 0.2627	0.1167 [-0.0302, 0.2637]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (5.3%)	0	1 (3.4%)	1.2857 [0.0309, 53.5122]	1.2000 [0.0768, 18.7451] 0.6171	0.0311 [-0.0492, 0.1115]
		Moderate	0	0	0			
Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 104 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>
							[95 %-CI] <sup>b</sup>	
Eye disorders	Astigmatism	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis allergic	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye haemorrhage	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypermetropia	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Myopia	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Strabismus	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 105 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Immune system disorders			1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
		Moderate	0	0	0			
	Seasonal allergy	Severe	0	0	0			
			1 (5.3%)	0	1 (3.4%)			
		Mild	1 (5.3%)	0	1 (3.4%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0584 [-0.0492, 0.1659]
	Allergy to animal	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Hypersensitivity	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 106 of 112



Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=10)	(N=29)	[95 %-CI] <sup>b</sup>		
Blood and lymphatic system disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Anaemia						
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Iron deficiency anaemia						
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Lymphadenopathy						
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Neutropenia						
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 107 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>
							[95 %-CI] <sup>b</sup>	
Cardiac disorders		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinoatrial block		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Sinus tachycardia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tachycardia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Hepatobiliary disorders		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		0	0	0				
		0	0	0				
		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 108 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=10)	Total (N=29)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Hepatobiliary disorders	Hepatomegaly		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Metabolism and nutrition disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Polydipsia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Psychiatric disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 109 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=10)	(N=29)	[95 %-CI] <sup>b</sup>		
Psychiatric disorders	Affect lability		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Attention deficit/hyperactivity disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Depressive symptom		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Enuresis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 110 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=10)	(N=29)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Renal and urinary disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Pollakiuria		0	0	0		
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Polyuria		0	0	0		
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Reproductive system and breast disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 111 of 112

Table 1.30 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender  
Safety Population

Female			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
			(N=19)	(N=10)	(N=29)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>	
Reproductive system and breast disorders	Genital discomfort		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Penile adhesion	Severe	0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
Any adverse event			32 (86.5%)	17 (81.0%)	49 (84.5%)				
		Mild	19 (51.4%)	11 (52.4%)	30 (51.7%)	1.0078 [0.3381, 3.0037]	1.0036 [0.6058, 1.6627]	0.0019 [-0.2616, 0.2654]	0.1218
		Moderate	13 (35.1%)	6 (28.6%)	19 (32.8%)	1.2687 [0.3662, 4.3952]	1.1538 [0.5414, 2.4591]	0.0449 [-0.1869, 0.2768]	0.1335
		Severe	0	0	0		0.7121		0.9786
Infections and infestations			25 (67.6%)	13 (61.9%)	38 (65.5%)				
		Mild	15 (40.5%)	10 (47.6%)	25 (43.1%)	0.7550 [0.2565, 2.2221]	0.8538 [0.4681, 1.5573]	-0.0693 [-0.3359, 0.1973]	0.3020
		Moderate	10 (27.0%)	3 (14.3%)	13 (22.4%)	2.1726 [0.4844, 9.7439]	1.7407 [0.5894, 5.1410]	0.1124 [-0.0866, 0.3113]	0.0161
		Severe	0	0	0		0.3096		0.9786
	Nasopharyngitis		7 (18.9%)	3 (14.3%)	10 (17.2%)				
	Mild	6 (16.2%)	3 (14.3%)	9 (15.5%)	1.1385 [0.2544, 5.0943]	1.1200 [0.2965, 4.2309]	0.0169 [-0.1754, 0.2091]	0.5419	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 1 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Nasopharyngitis	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9482
		Severe	0	0	0		0.4386		
	Pharyngitis	Mild	3 (8.1%)	5 (23.8%)	8 (13.8%)	0.1369 [0.0205, 0.9157]	0.2061 [0.0457, 0.9292]	-0.1948 [-0.3858, -0.0037]	0.2230
		Moderate	2 (5.4%)	5 (23.8%)	7 (12.1%)		0.0262		
	Upper respiratory tract infection	Moderate	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [-0.0255, 0.0705]	0.9718
		Severe	1 (2.7%)	4 (19.0%)	5 (8.6%)		0.5127		
	Mild	1 (2.7%)	3 (14.3%)	4 (6.9%)	0.1724 [0.0165, 1.8032]	0.2000 [0.0225, 1.7807]	-0.1124 [-0.2699, 0.0452]	0.9615	
	Moderate	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640]	-0.0468 [-0.1373, 0.0437]	0.9991	
	Severe	0	0	0		0.1967			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 2 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Ear infection		3 (8.1%)	1 (4.8%)	4 (6.9%)				
		Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132]	-0.0187 [-0.1234, 0.0860]	0.9990
		Moderate	2 (5.4%)	0	2 (3.4%)	1.7513 [0.1640, 18.7003]	0.7121 1.6507 [0.1905, 14.3072]	0.0506 [-0.0204, 0.1215]	0.9988
		Severe	0	0	0		0.3113		
	Respiratory tract infection		2 (5.4%)	2 (9.5%)	4 (6.9%)				
		Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.4800 [0.0253, 9.1006]	0.4800 [0.0235, 9.8096]	-0.0243 [-0.1281, 0.0794]	0.4651
		Moderate	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5357 [0.0387, 7.4152]	0.6259 0.5357 [0.0418, 6.8617]	-0.0243 [-0.1355, 0.0868]	0.9702
		Severe	0	0	0		0.6259		
	Bronchitis		2 (5.4%)	1 (4.8%)	3 (5.2%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [-0.0255, 0.0705]	0.9987

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 3 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37)			Genotropin n (N=21)			Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Infections and infestations	Bronchitis	Moderate	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.3333 [0.0136, 8.1825]	0.4286 [0.0381, 4.8169]	-0.0300 [-0.1276, 0.0677]	0.9686				
		Severe	0	0	0		0.5127						
	Gastroenteritis viral	Mild	3 (8.1%)	0	3 (5.2%)	2.3796 [0.2376, 23.8283]	2.1401 [0.2612, 17.5351]	0.0787 [-0.0085, 0.1658]	0.9785				
		Moderate	3 (8.1%)	0	3 (5.2%)		0.1992						
	Pharyngitis streptococcal	Severe	0	0	0								
		Mild	3 (8.1%)	0	3 (5.2%)	3.2456 [0.1474, 71.4889]	3.0645 [0.1553, 60.4653]	0.0562 [-0.0182, 0.1305]	0.9515				
		Moderate	2 (5.4%)	0	2 (3.4%)		0.2682						
		Severe	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9582				
		Severe	0	0	0		0.4386						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 4 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Infections and infestations	Viral infection		3 (8.1%)	0	3 (5.2%)					
		Mild	3 (8.1%)	0	3 (5.2%)	2.4338 [0.2384, 24.8441]	2.1842 [0.2707, 17.6229] 0.2110	0.0730 [-0.0114, 0.1575]	0.9978	
		Moderate	0	0	0				0.9786	
		Severe	0	0	0					
	Gastroenteritis			0	2 (9.5%)	2 (3.4%)				
		Mild	0	2 (9.5%)	2 (3.4%)	0.1488 [0.0137, 1.6155]	0.1834 [0.0212, 1.5897] 0.0468	-0.0993 [-0.2269, 0.0284]	0.9429	
		Moderate	0	0	0				0.9715	
		Severe	0	0	0					
	Influenza			1 (2.7%)	1 (4.8%)	2 (3.4%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755	
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718	
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 5 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Rhinitis		2 (5.4%)	0	2 (3.4%)				
		Mild	2 (5.4%)	0	2 (3.4%)	3.2456 [0.1474, 71.4889]	3.0645 [0.1553, 60.4653] 0.2682	0.0562 [-0.0182, 0.1305]	0.9773
		Moderate	0	0	0				
		Severe	0	0	0				
	Atypical pneumonia		1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0				
	Conjunctivitis		1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				0.9786
		Moderate	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515] 0.5127	0.0225 [-0.0255, 0.0705]	0.9718
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 6 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Conjunctivitis bacterial		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
		Moderate	0	0	0				
		Severe	0	0	0				
	Croup infectious		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)				
		Moderate	0	0	0				
		Severe	0	0	0				
	Cystitis		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				
	Enteritis infectious		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
Moderate		0	0	0				0.9731	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 7 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Enterobiasis		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9755
		Moderate	0	0	0				
		Severe	0	0	0				
	Helminthic infection		1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9482
		Severe	0	0	0				
	Hordeolum		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
Moderate		0	0	0					
Severe		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 8 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Laryngitis viral		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1111 [0.0033, 3.7020]	0.1667 [0.0086, 3.2391] 0.1266	-0.0524 [-0.1476, 0.0427]	0.9755
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis externa		1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0				
	Otitis media acute		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				0.9715
		Severe	0	0	0				
	Pharyngotonsillitis		1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				0.9715

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 9 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pharyngotonsillitis	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0	0.4386			
	Pneumonia	Mild	0	0	0				0.9582
		Moderate	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [-0.0255, 0.0705]	
	Respiratory tract infection viral	Severe	0	0	0	0.5127			0.9987
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	
	Rotavirus infection	Severe	0	0	0	0.4386			0.9718
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [-0.0255, 0.0705]	
		Moderate	0	0	0	0.5127			
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 10 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Sinusitis		1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				0.9963
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9987
	Tonsillitis	Severe	0	0	0				
		Mild	0	1 (4.8%)	1 (1.7%)				0.9786
		Moderate	0	1 (4.8%)	1 (1.7%)	0.1111 [0.0033, 3.7020]	0.1667 [0.0086, 3.2391] 0.1266	-0.0524 [-0.1476, 0.0427]	0.9755
	Viral upper respiratory tract infection	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9482
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 11 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)		Genotropin n (N=21)		Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value				
Infections and infestations	Vulvitis		1 (2.7%)	0	1 (1.7%)					
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515] 0.5127	0.0225 [-0.0255, 0.0705]	0.9718	
		Moderate	0	0	0					
	Appendicitis	Severe	0	0	0					
		Mild	0	0	0					
		Moderate	0	0	0					
	Eczema infected	Severe	0	0	0				0.9786	
		Mild	0	0	0				0.9786	
		Moderate	0	0	0					
	Infected bite	Severe	0	0	0					
		Mild	0	0	0				0.9786	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 12 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Infections and infestations	Molluscum contagiosum		0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Pulpitis dental		0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Tinea pedis		0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Tooth abscess		0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Urinary tract infection		0	0	0				
		Mild	0	0	0				
Moderate		0	0	0				0.9715	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 13 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)		Genotropin n (N=21)		Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
								OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Varicella		0		0		0				
		Mild	0		0		0				0.9786
		Moderate	0		0		0				0.9786
		Severe	0		0		0				
Gastrointestinal disorders			11 (29.7%)		3 (14.3%)		14 (24.1%)				
		Mild	10 (27.0%)		3 (14.3%)		13 (22.4%)	2.3714 [0.5589, 10.0615]	1.9600 [0.6077, 6.3219]	0.1348 [-0.0697, 0.3394]	0.8989
		Moderate	1 (2.7%)		0		1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9582
		Severe	0		0		0		0.2417	0.4386	
	Vomiting	Mild	4 (10.8%)		1 (4.8%)		5 (8.6%)	2.6154 [0.2689, 25.4418]	2.4000 [0.2904, 19.8345]	0.0655 [-0.0697, 0.2008]	0.9471
		Moderate	0		0		0				0.9715
		Severe	0		0		0				
			0		0		0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 14 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction n p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Abdominal pain		3 (8.1%)	1 (4.8%)	4 (6.9%)				
		Mild	2 (5.4%)	1 (4.8%)	3 (5.2%)	1.2143 [0.1022, 14.4270]	1.2000 [0.1170, 12.3119]	0.0094 [-0.1071, 0.1259]	0.9997
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718
	Diarrhoea	Severe	0	0	0		0.4386		
		Mild	2 (5.4%)	2 (9.5%)	4 (6.9%)	0.5714 [0.0733, 4.4564]	0.6000 [0.0924, 3.8962]	-0.0375 [-0.1818, 0.1069]	0.3760
		Moderate	0	0	0		0.5935		
	Nausea	Severe	0	0	0				
		Mild	2 (5.4%)	1 (4.8%)	3 (5.2%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132]	-0.0187 [-0.1234, 0.0860]	0.9766
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9482
		Severe	0	0	0		0.4386		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 15 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Abdominal pain upper		1 (2.7%)	1 (4.8%)	2 (3.4%)				
		Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132] 0.7121	-0.0187 [-0.1234, 0.0860]	0.9766
		Moderate	0	0	0				
	Abdominal discomfort	Severe	0	0	0				
			1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9987
	Constipation	Moderate	0	0	0				
		Severe	0	0	0				
			1 (2.7%)	0	1 (1.7%)				
	Dyspepsia	Mild	0	0	0				0.9797
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0				
			1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515] 0.5127	0.0225 [-0.0255, 0.0705]	0.9987
Moderate		0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Gastric disorder		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal motility disorder		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515] 0.5127	0.0225 [-0.0255, 0.0705]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				
	Aphthous ulcer		0	0	0				
		Mild	0	0	0				0.9715
		Moderate	0	0	0				
		Severe	0	0	0				
Lip swelling		0	0	0					
	Mild	0	0	0				0.9786	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 17 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Toothache		0	0	0				
		Mild	0	0	0				0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
Respiratory, thoracic and mediastinal disorders	Cough		10 (27.0%)	3 (14.3%)	13 (22.4%)				
		Mild	6 (16.2%)	3 (14.3%)	9 (15.5%)	1.1920 [0.2621, 5.4208]	1.1600 [0.3186, 4.2231]	0.0225 [-0.1678, 0.2128]	0.3954
		Moderate	4 (10.8%)	0	4 (6.9%)	2.9617 [0.3047, 28.7866]	0.8233 2.5639 [0.3214, 20.4551]	0.1067 [0.0069, 0.2066]	0.9724
		Severe	0	0	0		0.1294		
		Mild	4 (10.8%)	0	4 (6.9%)	2.9617 [0.3047, 28.7866]	2.5639 [0.3214, 20.4551]	0.1067 [0.0069, 0.2066]	0.9693
		Moderate	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [-0.0255, 0.0705]	0.9482
		Severe	0	0	0		0.5127		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 18 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Wheezing		2 (5.4%)	1 (4.8%)	3 (5.2%)				
		Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 0.7121 [0.0399, 9.0132]	-0.0187 [ -0.1234, 0.0860]	0.9990
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 0.4386 [0.0789, 42.8762]	0.0281 [ -0.0253, 0.0815]	0.9718
	Epistaxis	Severe	0	0	0				
		Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.1913 [0.0074, 4.9530]	0.2043 0.1967 [0.0088, 4.7640]	-0.0468 [ -0.1373, 0.0437]	0.9559
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 0.4386 [0.0789, 42.8762]	0.0281 [ -0.0253, 0.0815]	0.9718
	Nasal congestion	Severe	0	0	0				
		Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.1913 [0.0074, 4.9530]	0.2043 0.1967 [0.0088, 4.7640]	-0.0468 [ -0.1373, 0.0437]	0.9430

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 19 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37) vs. Genotropin n (N=21)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Nasal congestion	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0		0.4386		
		Respiratory disorder	1 (2.7%)	1 (4.8%)	2 (3.4%)				
	Allergic cough	Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132]	-0.0187 [-0.1234, 0.0860]	0.9702
		Moderate	0	0	0		0.7121		0.9985
		Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718
	Laryngospasm	Moderate	0	0	0		0.4386		
		Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 20 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Laryngospasm	Moderate	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [-0.0255, 0.0705]	0.9718
		Severe	0	0	0		0.5127		
	Paranasal sinus discomfort	Moderate	1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				
	Rhinorrhoea	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0		0.4386		
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640]	-0.0468 [-0.1373, 0.0437]	0.9991
		Moderate	0	0	0		0.1967		
	Sinus congestion	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0			0.9797	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 21 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Respiratory, thoracic and mediastinal disorders	Sinus congestion	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718	
		Severe	0	0	0		0.4386			
	Sleep apnoea syndrome	Moderate	1 (2.7%)	0	1 (1.7%)					
		Mild	0	0	0					
	Asthma	Moderate	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718
			Severe	0	0	0		0.4386		
		Mild	Mild	0	0	0				0.9786
			Moderate	0	0	0				0.9985
		Severe	Severe	0	0	0				
			Mild	0	0	0				
	Dyspnoea exertional	Moderate	Moderate	0	0	0				0.9786
			Moderate	0	0	0				
Severe			0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 22 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		0	0	0				0.9999
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
General disorders and administration site conditions			9 (24.3%)	3 (14.3%)	12 (20.7%)				
		Mild	7 (18.9%)	1 (4.8%)	8 (13.8%)	4.8500 [0.5435, 43.2798]	4.0800 [0.5308, 31.3602]	0.1442 [-0.0112, 0.2996]	
		Moderate	2 (5.4%)	2 (9.5%)	4 (6.9%)	0.5714 [0.0733, 4.4564]	0.6000 [0.0924, 3.8962]	-0.0375 [-0.1818, 0.1069]	
		Severe	0	0	0				
	Pyrexia	Mild	8 (21.6%)	1 (4.8%)	9 (15.5%)				0.2100
		Mild	6 (16.2%)	1 (4.8%)	7 (12.1%)	4.2500 [0.4680, 38.5985]	3.6000 [0.4706, 27.5414]	0.1217 [-0.0276, 0.2711]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 23 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37) Genotropin (N=21) Total (N=58)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
General disorders and administrative site conditions	Pyrexia	Moderate	2 (5.4%)	0	2 (3.4%)	3.2456 [0.1474, 71.4889]	3.0645 [0.1553, 60.4653]	0.0562 [-0.0182, 0.1305]	0.9988
		Severe	0	0	0		0.2682		
	Face oedema	Mild	0	0	0				
		Moderate	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640]	-0.0468 [-0.1373, 0.0437]	0.9755
		Severe	0	0	0				
	Fatigue	Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640]	-0.0468 [-0.1373, 0.0437]	
	Moderate	0	0	0					
	Gait disturbance	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [-0.0255, 0.0705]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				
	Moderate	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and administrative site conditions	Influenza like illness		0	1 (4.8%)	1 (1.7%)				
		Mild	0	0	0				
		Moderate	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
	Injection site atrophy	Severe	0	0	0				
			1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
	Injection site urticaria	Moderate	0	0	0				
		Severe	0	0	0				
			1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 25 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)		Genotropin (N=21)		Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
			n	(%)	n	(%)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
General disorders and administrative site conditions	Vaccination site pain		0		1 (4.8%)		1 (1.7%)				
		Mild	0		1 (4.8%)		1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
		Moderate	0		0		0				
	Injection site swelling	Severe	0		0		0				
		Mild	0		0		0				0.9715
		Moderate	0		0		0				
	Medical device discomfort	Severe	0		0		0				
		Mild	0		0		0				0.9715
		Moderate	0		0		0				
		Severe	0		0		0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 26 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders			5 (13.5%)	3 (14.3%)	8 (13.8%)				
		Mild	3 (8.1%)	3 (14.3%)	6 (10.3%)	0.5479 [0.1051, 2.8571]	0.5769 [0.1309, 2.5434]	-0.0618 [-0.2400, 0.1164]	0.6842
		Moderate	2 (5.4%)	0	2 (3.4%)	3.2456 [0.1474, 71.4889]	3.0645 [0.1553, 60.4653]	0.0562 [-0.0182, 0.1305]	0.9734
		Severe	0	0	0		0.4662 0.2682		
		Pain in extremity	4 (10.8%)	1 (4.8%)	5 (8.6%)				
		Mild	3 (8.1%)	1 (4.8%)	4 (6.9%)	1.8889 [0.1814, 19.6702]	1.8000 [0.2022, 16.0261]	0.0375 [-0.0891, 0.1640]	0.9708
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0		0.4386		
		Arthralgia	2 (5.4%)	1 (4.8%)	3 (5.2%)				
		Mild	2 (5.4%)	1 (4.8%)	3 (5.2%)	1.2143 [0.1022, 14.4270]	1.2000 [0.1170, 12.3119]	0.0094 [-0.1071, 0.1259]	0.9730
		Moderate	0	0	0		0.8789		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Back pain		1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
	Musculoskeletal pain	Severe	0	0	0				
		Mild	0	0	0				0.9786
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
	Neck mass	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
			Severe	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 28 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Neck pain		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9430
		Moderate	0	0	0				
	Pain in jaw	Severe	0	0	0				
			1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				
	Synovial cyst	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0				
			0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1111 [0.0033, 3.7020]	0.1667 [0.0086, 3.2391] 0.1266	-0.0524 [-0.1476, 0.0427]	0.9755
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 29 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Arthritis reactive		0	0	0				0.9786
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
Nervous system disorders	Headache		4 (10.8%)	4 (19.0%)	8 (13.8%)				0.4580
		Mild	3 (8.1%)	3 (14.3%)	6 (10.3%)	0.5556 [0.0995, 3.1034]	0.6000 [0.1353, 2.6617]	-0.0562 [-0.2282, 0.1158]	
		Moderate	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132]	-0.0187 [-0.1234, 0.0860]	
		Severe	0	0	0		0.5035 0.7121		
		Mild	3 (8.1%)	2 (9.5%)	5 (8.6%)	0.8889 [0.1339, 5.9018]	0.9000 [0.1659, 4.8828]	-0.0094 [-0.1617, 0.1429]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Nervous system disorders	Headache	Moderate	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132]	-0.0187 [-0.1234, 0.0860]	0.8545
		Severe	0	0	0		0.7121		
	Dizziness	Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132]	-0.0187 [-0.1234, 0.0860]	0.9702
		Moderate	0	0	0		0.7121		
	Migraine	Severe	0	0	0				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640]	-0.0468 [-0.1373, 0.0437]	0.9755
		Moderate	0	0	0		0.1967		
		Severe	0	0	0				
	Post-traumatic headache	Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9482
		Moderate	0	0	0		0.4386		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 31 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Nervous system disorders	Tremor		0	0	0					
		Mild	0	0	0					
		Moderate	0	0	0				0.9786	
		Severe	0	0	0					
Endocrine disorders			5 (13.5%)	2 (9.5%)	7 (12.1%)					
		Mild	5 (13.5%)	2 (9.5%)	7 (12.1%)	1.6000 [0.2764, 9.2608]	1.5000 [0.3241, 6.9423] 0.6014	0.0468 [-0.1188, 0.2124]	0.1426	
		Moderate	0	0	0				0.9797	
		Severe	0	0	0					
	Secondary hypothyroidism			4 (10.8%)	1 (4.8%)	5 (8.6%)				
			Mild	4 (10.8%)	1 (4.8%)	5 (8.6%)	2.6154 [0.2689, 25.4418]	2.4000 [0.2904, 19.8345] 0.3981	0.0655 [-0.0697, 0.2008]	0.3057
			Moderate	0	0	0				0.9786
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 32 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Secondary adrenocortical insufficiency		1 (2.7%)	1 (4.8%)	2 (3.4%)				
		Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132] 0.7121	-0.0187 [-0.1234, 0.0860]	0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Diabetes insipidus		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9482
		Moderate	0	0	0				
		Severe	0	0	0				
	Adrenal insufficiency		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9786
		Severe	0	0	0				
	Hypothyroidism		0	0	0				
		Mild	0	0	0				0.9715
Moderate		0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 33 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37) Genotropin (N=21) Total (N=58)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Injury, poisoning and procedural complications			5 (13.5%)	2 (9.5%)	7 (12.1%)				
		Mild	3 (8.1%)	2 (9.5%)	5 (8.6%)	0.8889 [0.1339, 5.9018]	0.9000 [0.1659, 4.8828]	-0.0094 [-0.1617, 0.1429]	0.8633
		Moderate	2 (5.4%)	0	2 (3.4%)	3.2456 [0.1474, 71.4889]	0.9039 3.0645 [0.1553, 60.4653]	0.0562 [-0.0182, 0.1305]	0.9792
		Severe	0	0	0		0.2682		
		Post-traumatic pain	1 (2.7%)	1 (4.8%)	2 (3.4%)				
		Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132]	-0.0187 [-0.1234, 0.0860]	0.9990
		Moderate	0	0	0		0.7121		
		Severe	0	0	0				
		Ankle fracture	1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				
	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718	
	Severe	0	0	0		0.4386			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 34 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Concussion		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
		Moderate	0	0	0				
	Contusion	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				0.9786
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
	Head injury	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				0.9718
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 35 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37)		Genotropin n (N=21)		Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>						
Injury, poisoning and procedural complications	Ligament sprain		1 (2.7%)	0	1 (1.7%)						
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718		
		Moderate	0	0	0						
	Thermal burn	Severe	0	0	0						
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755		
		Moderate	0	0	0						
	Upper limb fracture	Severe	0	0	0						
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718		
		Moderate	0	0	0						
		Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 36 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)			Genotropin n (N=21)			Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>							
Injury, poisoning and procedural complications	Animal bite		0	0	0								
		Mild	0	0	0							0.9985	
		Moderate	0	0	0								
		Severe	0	0	0								
		Arthropod bite		0	0	0							
		Mild	0	0	0							0.9985	
		Moderate	0	0	0								
		Severe	0	0	0								
		Burns first degree		0	0	0							
		Mild	0	0	0							0.9715	
		Moderate	0	0	0								
		Severe	0	0	0								
		Burns second degree		0	0	0							
		Mild	0	0	0								
		Moderate	0	0	0							0.9786	
		Severe	0	0	0								
		Face injury		0	0	0							
		Mild	0	0	0								
	Moderate	0	0	0							0.9786		
	Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 37 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)			Genotropin n (N=21)			Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Injury, poisoning and procedural complications	Fall		0	0	0								
		Mild	0	0	0						0.9786		
		Moderate	0	0	0								
	Laceration	Severe	0	0	0								
		Mild	0	0	0						0.9786		
		Moderate	0	0	0								
	Meniscus injury	Severe	0	0	0								
		Mild	0	0	0								
		Moderate	0	0	0						0.9715		
	Muscle strain	Severe	0	0	0								
		Mild	0	0	0								
		Moderate	0	0	0						0.9786		
	Radius fracture	Severe	0	0	0								
		Mild	0	0	0								
		Moderate	0	0	0						0.9786		
			Severe	0	0	0							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Wrist fracture		0	0	0				0.9786
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
Skin and subcutaneous tissue disorders			5 (13.5%)	1 (4.8%)	6 (10.3%)				
		Mild	4 (10.8%)	0	4 (6.9%)	2.9617 [0.3047, 28.7866]	2.5639 [0.3214, 20.4551]	0.1067 [0.0069, 0.2066]	0.9719
		Moderate	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.1294 0.6000 [0.0399, 9.0132]	-0.0187 [ -0.1234, 0.0860]	0.9737
	Cafe au lait spots	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [ -0.0255, 0.0705]	0.9718
		Moderate	0	0	0		0.5127		
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 39 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Eczema		1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
	Keratosis pilaris	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515] 0.5127	0.0225 [-0.0255, 0.0705]	0.9718
	Petechiae	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 40 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Pityriasis alba		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515] 0.5127	0.0225 [-0.0255, 0.0705]	0.9718
		Moderate	0	0	0				
	Rash	Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9741
	Rash erythematous	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
	Rash pruritic	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	0	1 (4.8%)	1 (1.7%)				
		Mild	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 41 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)		Genotropin n (N=21)		Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value				
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640]	-0.0468 [-0.1373, 0.0437]	0.9755	
		Severe	0	0	0					
	Dermatitis allergic	Mild	0	0	0					
		Moderate	0	0	0					
		Severe	0	0	0				0.9715	
	Dermatitis contact	Mild	0	0	0					
		Moderate	0	0	0					
		Severe	0	0	0				0.9786	
	Urticaria	Mild	0	0	0					
		Moderate	0	0	0				0.9786	
		Severe	0	0	0				0.9715	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 42 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity				Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Eye disorders			3 (8.1%)	2 (9.5%)	5 (8.6%)				
		Mild	3 (8.1%)	2 (9.5%)	5 (8.6%)	0.8286 [0.1259, 5.4537]	0.8400 [0.1438, 4.9061] 0.8479	-0.0150 [-0.1681, 0.1381]	0.9688
		Moderate	0	0	0				
		Severe	0	0	0				
		Conjunctivitis allergic	1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				
		Eye swelling	1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515] 0.5127	0.0225 [-0.0255, 0.0705]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypermetropia	1 (2.7%)	0	1 (1.7%)					
	Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 43 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37) Genotropin (N=21) Total (N=58)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value	
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>					
Eye disorders	Myopia		0	1 (4.8%)	1 (1.7%)					
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755	
		Moderate	0	0	0					
		Severe	0	0	0					
	Strabismus			0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9430	
		Moderate	0	0	0					
		Severe	0	0	0					
	Astigmatism			0	0	0				
		Mild	0	0	0				0.9786	
		Moderate	0	0	0					
		Severe	0	0	0					
	Eye haemorrhage			0	0	0				
		Mild	0	0	0				0.9786	
Moderate		0	0	0						
	Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 44 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations			3 (8.1%)	2 (9.5%)	5 (8.6%)				
		Mild	3 (8.1%)	2 (9.5%)	5 (8.6%)	0.8889 [0.1339, 5.9018]	0.9000 [0.1659, 4.8828] 0.9039	-0.0094 [-0.1617, 0.1429]	0.4266
		Moderate	0	0	0				
		Severe	0	0	0				
	Alanine aminotransferase increased		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
		Moderate	0	0	0				
		Severe	0	0	0				
	Aspartate aminotransferase increased		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 45 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Blood cortisol decreased		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood iron decreased		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood thyroid stimulating hormone increased		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 46 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Cortisol free urine decreased		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
	Thyroxine decreased	Severe	0	0	0				
			0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755
	Transaminases increased	Moderate	0	0	0				
		Severe	0	0	0				
			1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 47 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37) Genotropin (N=21) Total (N=58)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Investigations	Blood iron increased		0	0	0				
		Mild	0	0	0				0.9715
		Moderate	0	0	0				
	Eosinophil count increased	Severe	0	0	0				
		Mild	0	0	0				0.9797
		Moderate	0	0	0				
	Insulin-like growth factor increased	Severe	0	0	0				
		Mild	0	0	0				0.9797
		Moderate	0	0	0				
	White blood cell count decreased	Severe	0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 48 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction n p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders			4 (10.8%)	0	4 (6.9%)				
		Mild	2 (5.4%)	0	2 (3.4%)	3.2456 [0.1474, 71.4889]	3.0645 [0.1553, 60.4653]	0.0562 [-0.0182, 0.1305]	0.9766
		Moderate	2 (5.4%)	0	2 (3.4%)	1.7513 [0.1640, 18.7003]	1.6507 [0.1905, 14.3072]	0.0506 [-0.0204, 0.1215]	0.9734
		Severe	0	0	0		0.2682 0.3113		
		Iron deficiency anaemia	2 (5.4%)	0	2 (3.4%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9987
		Moderate	1 (2.7%)	0	1 (1.7%)	1.6154 [0.0511, 51.1064]	1.5000 [0.0772, 29.1515]	0.0225 [-0.0255, 0.0705]	0.9718
		Severe	0	0	0		0.5127		
		Lymphadenopathy	1 (2.7%)	0	1 (1.7%)				
		Mild	0	0	0				0.9715

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 49 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)		Genotropin n (N=21)		Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718	
		Severe	0	0	0	0.4386				
	Neutropenia	Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9987	
		Moderate	0	0	0	0.4386				
	Anaemia	Severe	0	0	0					
		Mild	0	0	0					
		Moderate	0	0	0					
		Severe	0	0	0					
	Ear and labyrinth disorders			3 (8.1%)	0	3 (5.2%)				
		Mild		3 (8.1%)	0	3 (5.2%)	2.3796 [0.2376, 23.8283]	2.1401 [0.2612, 17.5351]	0.0787 [-0.0085, 0.1658]	0.9967
Moderate			0	0	0	0.1992				
	Severe		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 50 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Ear and labyrinth disorders	Ear pain		3 (8.1%)	0	3 (5.2%)				
		Mild	3 (8.1%)	0	3 (5.2%)	2.3796 [0.2376, 23.8283]	2.1401 [0.2612, 17.5351] 0.1992	0.0787 [-0.0085, 0.1658]	0.9967
		Moderate	0	0	0				
		Severe	0	0	0				
Immune system disorders			3 (8.1%)	0	3 (5.2%)				
		Mild	2 (5.4%)	0	2 (3.4%)	3.2456 [0.1474, 71.4889]	3.0645 [0.1553, 60.4653] 0.2682	0.0562 [-0.0182, 0.1305]	0.9758
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
	Seasonal allergy		0	0	0				
		Mild	2 (5.4%)	0	2 (3.4%)	3.2456 [0.1474, 71.4889]	3.0645 [0.1553, 60.4653] 0.2682	0.0562 [-0.0182, 0.1305]	0.9697
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 51 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Immune system disorders	Hypersensitivity		1 (2.7%)	0	1 (1.7%)					
		Mild	0	0	0				0.9715	
		Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718	
	Allergy to animal	Severe	0	0	0					
			0	0	0					
		Mild	0	0	0				0.9797	
		Moderate	0	0	0					
		Severe	0	0	0					
	Psychiatric disorders			1 (2.7%)	1 (4.8%)	2 (3.4%)				
			Mild	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.5862 [0.0344, 9.9906]	0.6000 [0.0399, 9.0132] 0.7121	-0.0187 [-0.1234, 0.0860]	0.9766
		Moderate	0	0	0				0.9786	
		Severe	0	0	0					
Affect lability			1 (2.7%)	0	1 (1.7%)					
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718	
		Moderate	0	0	0					
	Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 52 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Psychiatric disorders	Attention deficit/hyperactivity disorder		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9430
		Moderate	0	0	0				
		Severe	0	0	0				
	Depressive symptom		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9786
		Severe	0	0	0				
	Enuresis		0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
Cardiac disorders			1 (2.7%)	0	1 (1.7%)				
	Mild	0	0	0				0.9786	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 53 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=37) vs. Genotropin n (N=21)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>			
Cardiac disorders	Sinus tachycardia	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0				
		Mild	1 (2.7%)	0	1 (1.7%)				
	Sinoatrial block	Moderate	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Severe	0	0	0				
		Mild	0	0	0				0.9786
	Tachycardia	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	0	0	0				0.9786
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 54 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Hepatobiliary disorders			0	1 (4.8%)	1 (1.7%)					
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755	
		Moderate	0	0	0					
		Severe	0	0	0					
		Hepatomegaly		1 (4.8%)	1 (1.7%)					
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9755	
		Moderate	0	0	0					
		Severe	0	0	0					
	Metabolism and nutrition disorders			1 (2.7%)	0	1 (1.7%)				
			Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 55 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Metabolism and nutrition disorders	Polydipsia		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9495
		Moderate	0	0	0				
		Severe	0	0	0				
Skin papilloma			0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9559
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=37) Genotropin (N=21) Total (N=58)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
Renal and urinary disorders			1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9987
		Moderate	0	0	0				
	Polyuria		1 (2.7%)	0	1 (1.7%)				
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9718
		Moderate	0	0	0				
		Severe	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 57 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: ≤ 5 ng/mL

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Renal and urinary disorders	Pollakiuria		0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
Reproductive system and breast disorders	Penile adhesion		0	1 (4.8%)	1 (1.7%)				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9991
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	0	1 (4.8%)	1 (1.7%)	0.1913 [0.0074, 4.9530]	0.2043 [0.0088, 4.7640] 0.1967	-0.0468 [-0.1373, 0.0437]	0.9991
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 58 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: <= 5 ng/mL

System Organ Class	Preferred Term	Severity	Baseline GH-stimulation strata: <= 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=37)	Genotropin n (N=21)	Total (N=58)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Reproductive system and breast disorders	Genital discomfort		0	0	0					
		Mild	0	0	0				0.9715	
		Moderate	0	0	0					
		Severe	0	0	0					
Vascular disorders			1 (2.7%)	0	1 (1.7%)					
		Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9987	
		Moderate	0	0	0					
		Severe	0	0	0					
	Hypotension			1 (2.7%)	0	1 (1.7%)				
			Mild	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762] 0.4386	0.0281 [-0.0253, 0.0815]	0.9987
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 59 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Any adverse event			49 (72.1%)	22 (62.9%)	71 (68.9%)			
	Mild		34 (50.0%)	9 (25.7%)	43 (41.7%)	2.9984 [1.2114, 7.4215]	1.9752 [1.0694, 3.6483] 0.0165	0.2480 [0.0622, 0.4338]
	Moderate		14 (20.6%)	13 (37.1%)	27 (26.2%)	0.4264 [0.1717, 1.0586]	0.5460 [0.2902, 1.0272] 0.0651	-0.1698 [-0.3559, 0.0163]
	Severe		1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Infections and infestations		31 (45.6%)	19 (54.3%)	50 (48.5%)			
	Mild		24 (35.3%)	9 (25.7%)	33 (32.0%)	1.6087 [0.6483, 3.9915]	1.3900 [0.7285, 2.6522] 0.3068	0.1001 [-0.0839, 0.2842]
	Moderate		6 (8.8%)	10 (28.6%)	16 (15.5%)	0.2368 [0.0772, 0.7266]	0.3035 [0.1193, 0.7724] 0.0088	-0.1992 [-0.3632, -0.0352]
	Severe		1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 60 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Pharyngitis		7 (10.3%)	5 (14.3%)	12 (11.7%)			
		Mild	7 (10.3%)	5 (14.3%)	12 (11.7%)	0.6839 [0.2010, 2.3277]	0.7162 [0.2467, 2.0793] 0.5437	-0.0409 [-0.1782, 0.0964]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasopharyngitis		5 (7.4%)	5 (14.3%)	10 (9.7%)			
		Mild	5 (7.4%)	4 (11.4%)	9 (8.7%)	0.6272 [0.1584, 2.4824]	0.6540 [0.1895, 2.2565] 0.5041	-0.0398 [-0.1630, 0.0835]
		Moderate	0	1 (2.9%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579] 0.2008	-0.0269 [-0.0807, 0.0268]
	Respiratory tract infection	Severe	0	0	0			
		Mild	5 (7.4%)	1 (2.9%)	6 (5.8%)			
			Mild	4 (5.9%)	1 (2.9%)	5 (4.9%)	2.1879 [0.2572, 18.6143]	2.1641 [0.2658, 17.6209] 0.4508

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 61 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			Genotropin n (N=35)	Total (N=103)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Respiratory tract infection	Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
		Severe	0	0	0		0.4884	
		Mild	5 (7.4%)	1 (2.9%)	6 (5.8%)			
		Moderate	5 (7.4%)	0	5 (4.9%)	3.5497 [0.4068, 30.9775]	3.2929 [0.4128, 26.2663]	0.0751 [0.0124, 0.1379]
		Severe	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693]	-0.0293 [-0.0852, 0.0266]
		Mild	3 (4.4%)	0	3 (2.9%)			
	Gastroenteritis	Mild	3 (4.4%)	0	3 (2.9%)	3.6105 [0.1792, 72.7389]	3.4314 [0.1843, 63.8959]	0.0422 [-0.0057, 0.0902]
		Moderate	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693]	-0.0293 [-0.0852, 0.0266]
		Severe	0	0	0		0.1489	
		Mild	3 (4.4%)	0	3 (2.9%)			
		Moderate	0	1 (2.9%)	1 (1.0%)			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 62 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Pharyngitis and streptococcal		0	4 (11.4%)	4 (3.9%)			
		Mild	0	2 (5.7%)	2 (1.9%)	0.0891 [0.0041, 1.9325]	0.0980 [0.0049, 1.9661]	-0.0586 [-0.1365, 0.0192]
		Moderate	0	2 (5.7%)	2 (1.9%)	0.0891 [0.0041, 1.9325]	0.0398 [0.0049, 1.9661]	-0.0586 [-0.1365, 0.0192]
	Respiratory tract infection viral	Severe	0	0	0		0.0398	
			2 (2.9%)	2 (5.7%)	4 (3.9%)			
		Mild	2 (2.9%)	2 (5.7%)	4 (3.9%)	0.4897 [0.0647, 3.7069]	0.5004 [0.0685, 3.6561]	-0.0281 [-0.1145, 0.0583]
	Rhinitis	Moderate	0	0	0		0.4886	
		Severe	0	0	0			
			2 (2.9%)	2 (5.7%)	4 (3.9%)			
		Mild	2 (2.9%)	2 (5.7%)	4 (3.9%)	0.5413 [0.0692, 4.2321]	0.5668 [0.0814, 3.9475]	-0.0233 [-0.1074, 0.0607]
		Moderate	0	0	0		0.5654	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 63 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Sinusitis		2 (2.9%)	2 (5.7%)	4 (3.9%)			
		Mild	1 (1.5%)	2 (5.7%)	3 (2.9%)	0.2807 [0.0273, 2.8873]	0.2807 [0.0297, 2.6551]	-0.0422 [-0.1267, 0.0424]
		Moderate	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0165 [-0.0138, 0.0468]
	Bronchitis	Severe	0	0	0		0.4344	
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
		Moderate	0	2 (5.7%)	2 (1.9%)	0.1710 [0.0170, 1.7186]	0.1858 [0.0202, 1.7127]	-0.0563 [-0.1327, 0.0202]
	Viral infection	Severe	0	0	0		0.0545	
		Mild	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515]	0.0281 [-0.0113, 0.0676]
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
		Severe	0	0	0		0.4884	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 64 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Ear infection		2 (2.9%)	0	2 (1.9%)			
		Mild	0	0	0			
		Moderate	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515] 0.3239	0.0281 [-0.0113, 0.0676]
	Enteritis infectious	Severe	0	0	0			
		Mild	0	2 (5.7%)	2 (1.9%)			
		Moderate	0	2 (5.7%)	2 (1.9%)	0.1710 [0.0170, 1.7186]	0.1858 [0.0202, 1.7127] 0.0545	-0.0563 [-0.1327, 0.0202]
	Enterobiasis	Severe	0	0	0			
		Mild	1 (1.5%)	1 (2.9%)	2 (1.9%)	0.4694 [0.0281, 7.8413]	0.4800 [0.0313, 7.3505] 0.5931	-0.0152 [-0.0776, 0.0471]
		Moderate	1 (1.5%)	1 (2.9%)	2 (1.9%)			
	Pneumonia	Severe	0	0	0			
		Mild	0	2 (5.7%)	2 (1.9%)			
		Moderate	0	2 (5.7%)	2 (1.9%)	0.0891 [0.0041, 1.9325]	0.0980 [0.0049, 1.9661] 0.0398	-0.0586 [-0.1365, 0.0192]
Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 65 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Varicella		2 (2.9%)	0	2 (1.9%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Appendicitis	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]	
		Conjunctivitis	1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Moderate	0	0	0				
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 66 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Eczema infected		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
	Helminthic infection	Severe	0	0	0			
			0	1 (2.9%)	1 (1.0%)			
		Mild	0	0	0			
	Moderate		0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
		Severe	0	0	0			
			0	0	0			
	Infected bite		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
Severe		0	0	0				
		0	0	0				
		1 (1.5%)	0	1 (1.0%)				
Molluscum contagiosum		1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]	
	Mild	1 (1.5%)	0	1 (1.0%)				
	Moderate	0	0	0				
Severe		0	0	0				
		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 67 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropi n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Otitis media acute		0	1 (2.9%)	1 (1.0%)			
		Mild	0	0	0			
		Moderate	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
	Pharyngotonsillitis		0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
		Moderate	0	0	0			
	Pulpitis dental		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
	Tinea pedis		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 68 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Tonsillitis		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
	Tooth abscess	Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Urinary tract infection	Moderate	0	0	0			
		Severe	0	0	0			
			0	1 (2.9%)	1 (1.0%)			
		Mild	0	0	0			
		Moderate	0	1 (2.9%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579] 0.2008	-0.0269 [-0.0807, 0.0268]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 69 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=35) Total (N=103)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>			
Infections and infestations	Viral upper respiratory tract infection		0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
		Moderate	0	0	0			
		Severe	0	0	0			
	Atypical pneumonia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Croup infectious		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 70 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Cystitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Gastroenteritis viral	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Hordeolum	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Influenza	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Laryngitis viral	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 71 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68) Genotropin n (N=35) Total (N=103)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>			
Infections and infestations	Otitis externa		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Rotavirus infection	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Vulvitis	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Respiratory, thoracic and mediastinal disorders	Mild	17 (25.0%)	5 (14.3%)	22 (21.4%)			
		Moderate	14 (20.6%)	3 (8.6%)	17 (16.5%)	2.8269 [0.7540, 10.5995]	2.4419 [0.7548, 7.8996]	0.1234 [-0.0105, 0.2573]
		Severe	3 (4.4%)	2 (5.7%)	5 (4.9%)	0.7507 [0.1221, 4.6139]	0.7607 [0.1375, 4.2076]	-0.0140 [-0.1064, 0.0783]
		0	0	0		0.7552		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 72 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Cough		5 (7.4%)	4 (11.4%)	9 (8.7%)			
		Mild	5 (7.4%)	3 (8.6%)	8 (7.8%)	0.8449 [0.1952, 3.6574]	0.8543 [0.2216, 3.2937]	-0.0128 [-0.1268, 0.1011]
		Moderate	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.8196 0.1634 [0.0069, 3.8693]	-0.0293 [-0.0852, 0.0266]
	Asthma	Severe	0	0	0		0.1489	
		Mild	2 (2.9%)	1 (2.9%)	3 (2.9%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
		Moderate	1 (1.5%)	0	1 (1.0%)	0.5614 [0.0377, 8.3605]	0.4884 0.5614 [0.0413, 7.6362]	-0.0129 [-0.0771, 0.0514]
	Respiratory disorder	Severe	0	0	0		0.6603	
		Mild	2 (2.9%)	1 (2.9%)	3 (2.9%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0165 [-0.0138, 0.0468]
			1 (1.5%)	0	1 (1.0%)		0.4344	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 73 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=68)	n (N=35)	Total (N=103)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	1 (1.5%)	1 (2.9%)	2 (1.9%)	0.4694 [0.0281, 7.8413]	0.4800 [0.0313, 7.3505]	-0.0152 [-0.0776, 0.0471]
		Severe	0	0	0		0.5931	
		Mild	2 (2.9%)	1 (2.9%)	3 (2.9%)	1.0450 [0.0885, 12.3431]	1.0450 [0.0828, 13.1897]	0.0012 [-0.0663, 0.0687]
	Rhinitis allergic	Moderate	0	0	0		0.9727	
		Severe	0	0	0			
		Mild	2 (2.9%)	0	2 (1.9%)	1.7073 [0.1701, 17.1317]	1.6724 [0.1814, 15.4143]	0.0305 [-0.0104, 0.0715]
	Epistaxis	Moderate	0	0	0		0.2967	
		Severe	0	0	0			
		Mild	2 (2.9%)	0	2 (1.9%)	1.7073 [0.1701, 17.1317]	1.6724 [0.1814, 15.4143]	0.0305 [-0.0104, 0.0715]
	Sinus congestion	Moderate	0	0	0		0.2967	
		Severe	0	0	0			
		Mild	2 (2.9%)	0	2 (1.9%)	1.7073 [0.1701, 17.1317]	1.6724 [0.1814, 15.4143]	0.0305 [-0.0104, 0.0715]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 74 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		1 (1.5%)	0	1 (1.0%)			
		Mild	0	0	0			
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Nasal congestion	Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Rhinorrhoea	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	0	1 (2.9%)	1 (1.0%)			
	Allergic cough	Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
		Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 75 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Paranasal sinus discomfort	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Sleep apnoea syndrome	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Wheezing	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 76 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders			13 (19.1%)	5 (14.3%)	18 (17.5%)				
		Mild	13 (19.1%)	3 (8.6%)	16 (15.5%)	2.4472 [0.6683, 8.9612]	2.2156 [0.6853, 7.1636]	0.1069 [-0.0281, 0.2420]	
		Moderate	0	2 (5.7%)	2 (1.9%)	0.0891 [0.0041, 1.9325]	0.0980 [0.0049, 1.9661]	-0.0586 [-0.1365, 0.0192]	
		Severe	0	0	0		0.1609 0.0398		
		Vomiting		5 (7.4%)	2 (5.7%)	7 (6.8%)			
		Mild	5 (7.4%)	1 (2.9%)	6 (5.8%)	2.6625 [0.3089, 22.9463]	2.5628 [0.3229, 20.3388]	0.0458 [-0.0387, 0.1304]	
		Moderate	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693]	-0.0293 [-0.0852, 0.0266]	
		Severe	0	0	0		0.3534 0.1489		
		Diarrhoea		4 (5.9%)	1 (2.9%)	5 (4.9%)			
		Mild	4 (5.9%)	1 (2.9%)	5 (4.9%)	2.0653 [0.2245, 18.9969]	2.0014 [0.2396, 16.7141]	0.0294 [-0.0498, 0.1085]	
		Moderate	0	0	0		0.5142		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 77 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Nausea		2 (2.9%)	1 (2.9%)	3 (2.9%)			
		Mild	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515]	0.0281 [-0.0113, 0.0676]
		Moderate	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693]	-0.0293 [-0.0852, 0.0266]
	Abdominal pain upper	Severe	0	0	0		0.3239	
		Mild	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515]	0.0281 [-0.0113, 0.0676]
		Moderate	0	0	0		0.1489	
	Constipation	Severe	0	0	0			
		Mild	2 (2.9%)	0	2 (1.9%)	1.7073 [0.1701, 17.1317]	1.6724 [0.1814, 15.4143]	0.0305 [-0.0104, 0.0715]
		Moderate	0	0	0		0.2967	
	Toothache	Severe	0	0	0			
		Mild	1 (1.5%)	1 (2.9%)	2 (1.9%)	0.4694 [0.0281, 7.8413]	0.4800 [0.0313, 7.3505]	-0.0152 [-0.0776, 0.0471]
		Moderate	0	0	0		0.5931	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 78 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Abdominal discomfort		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
	Aphthous ulcer	Severe	0	0	0			
			0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
	Dyspepsia	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
	Lip swelling	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 79 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=35)			Total (N=103)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Gastrointestinal disorders	Abdominal pain	Mild	0	0	0									
		Moderate	0	0	0									
		Severe	0	0	0									
	Gastric disorder	Mild	0	0	0									
		Moderate	0	0	0									
		Severe	0	0	0									
	Gastrointestinal motility disorder	Mild	0	0	0									
		Moderate	0	0	0									
		Severe	0	0	0									
	General disorders and administration site conditions			9 (13.2%)	6 (17.1%)	15 (14.6%)								
		Mild	7 (10.3%)	6 (17.1%)	13 (12.6%)	0.5494 [0.1702, 1.7736]	0.5952 [0.2184, 1.6222]	0.3133	-0.0702 [-0.2154, 0.0749]					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 80 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=68)	n (N=35)	Total (N=103)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions	Pyrexia	Moderate	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515]	0.0281 [-0.0113, 0.0676]
		Severe	0	0	0		0.3239	
		Mild	8 (11.8%)	4 (11.4%)	12 (11.7%)	0.7551 [0.1992, 2.8624]	0.7765 [0.2361, 2.5542]	-0.0257 [-0.1515, 0.1001]
	Fatigue	Moderate	6 (8.8%)	4 (11.4%)	10 (9.7%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515]	0.0281 [-0.0113, 0.0676]
		Severe	0	0	0		0.3239	
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
		Moderate	1 (1.5%)	0	1 (1.0%)		0.4884	
		Severe	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 81 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and site swelling administration site conditions	Injection		0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
		Moderate	0	0	0			
	Medical device discomfort	Severe	0	0	0			
			0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
	Face oedema	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon Genotropin			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			hGH (N=68)	n (N=35)	Total (N=103)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and disturbance administration site conditions	Gait disorders and disturbance administration site conditions		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Influenza like illness	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Injection site atrophy	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Injection site urticaria	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 83 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=68)	n (N=35)	Total (N=103)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and site pain administration site conditions	Vaccination		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Nervous system disorders	Headache		10 (14.7%)	5 (14.3%)	15 (14.6%)			
		Mild	7 (10.3%)	3 (8.6%)	10 (9.7%)	1.1672 [0.2798, 4.8683]	1.1471 [0.3237, 4.0657] 0.8326	0.0129 [-0.1041, 0.1300]
		Moderate	3 (4.4%)	2 (5.7%)	5 (4.9%)	0.7021 [0.1094, 4.5078]	0.7200 [0.1287, 4.0278] 0.7100	-0.0164 [-0.1069, 0.0741]
		Severe	0	0	0			
		Mild	6 (8.8%)	2 (5.7%)	8 (7.8%)	1.5341 [0.2920, 8.0592]	1.4807 [0.3226, 6.7954] 0.6123	0.0282 [-0.0740, 0.1304]

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 84 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders	Headache	Moderate	3 (4.4%)	2 (5.7%)	5 (4.9%)	0.7021 [0.1094, 4.5078]	0.7200 [0.1287, 4.0278]	-0.0164 [-0.1069, 0.0741]
		Severe	0	0	0		0.7100	
	Dizziness	Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0		0.4884	
	Post-traumatic headache	Severe	0	0	0			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693]	-0.0293 [-0.0852, 0.0266]
	Tremor	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0		0.4884	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 85 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL						Lonapegsomatropin vs. Genotropina <sup>a</sup>		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropi n (N=35)	Total (N=103)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders	Migraine		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Injury, poisoning and procedural complications	Animal bite		9 (13.2%)	4 (11.4%)	13 (12.6%)			
		Mild	6 (8.8%)	3 (8.6%)	9 (8.7%)	0.9857 [0.2301, 4.2226]	0.9871 [0.2689, 3.6240]	-0.0011 [-0.1157, 0.1134]
		Moderate	3 (4.4%)	1 (2.9%)	4 (3.9%)	1.5431 [0.1582, 15.0523]	0.9846 1.5214 [0.1706, 13.5706]	0.0153 [ -0.0594, 0.0899]
		Severe	0	0	0		0.7064	
		Mild	1 (1.5%)	1 (2.9%)	2 (1.9%)	0.4694 [0.0281, 7.8413]	0.4800 [0.0313, 7.3505]	-0.0152 [-0.0776, 0.0471]
		Moderate	0	0	0		0.5931	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and bite procedural complications	Arthropod		1 (1.5%)	1 (2.9%)	2 (1.9%)				
		Mild	1 (1.5%)	1 (2.9%)	2 (1.9%)	0.4694 [0.0281, 7.8413]	0.4800 [0.0313, 7.3505] 0.5931	-0.0152 [-0.0776, 0.0471]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Burns first degree		0	1 (2.9%)	1 (1.0%)			
			Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
			Moderate	0	0	0			
		Burns second degree		1 (1.5%)	0	1 (1.0%)			
			Mild	0	0	0			
			Moderate	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 87 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Contusion		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
	Face injury	Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
		Mild	0	0	0			
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Severe	0	0	0			
		Fall	1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
		Severe	0	0	0			
	Laceration		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 88 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and injury procedural complications	Meniscus		0	1 (2.9%)	1 (1.0%)			
		Mild	0	0	0			
		Moderate	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
	Muscle strain	Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)			
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Radius fracture	Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 89 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and fracture procedural complications	Wrist fracture		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			
	Ankle fracture		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Concussion		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Head injury		0	0	0			
Mild		0	0	0				
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 90 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Ligament sprain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Post-traumatic pain	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Thermal burn	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Upper limb fracture	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 91 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders			4 (5.9%)	4 (11.4%)	8 (7.8%)				
		Mild	2 (2.9%)	4 (11.4%)	6 (5.8%)	0.2443 [0.0431, 1.3863]	0.2658 [0.0526, 1.3425] 0.0875	-0.0844 [-0.1980, 0.0292]	
		Moderate	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515] 0.3239	0.0281 [-0.0113, 0.0676]	
		Severe	0	0	0				
		Secondary hypothyroidism		3 (4.4%)	2 (5.7%)	5 (4.9%)			
		Mild	2 (2.9%)	2 (5.7%)	4 (3.9%)	0.5252 [0.0701, 3.9348]	0.5428 [0.0808, 3.6448] 0.5290	-0.0257 [-0.1121, 0.0606]	
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]	
		Severe	0	0	0				
		Adrenal insufficiency		1 (1.5%)	0	1 (1.0%)			
		Mild	0	0	0				
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]	
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Diabetes insipidus		0	1 (2.9%)	1 (1.0%)				
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypothyroidism			0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Secondary adrenocortical insufficiency			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 93 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders			5 (7.4%)	3 (8.6%)	8 (7.8%)			
		Mild	5 (7.4%)	3 (8.6%)	8 (7.8%)	0.8385 [0.1874, 3.7516]	0.8502 [0.2135, 3.3851] 0.8196	-0.0128 [-0.1243, 0.0987]
		Moderate	0	0	0			
		Severe	0	0	0			
		Arthralgia						
		Mild	3 (4.4%)	0	3 (2.9%)	2.2498 [0.2383, 21.2441]	2.1658 [0.2495, 18.8034] 0.2084	0.0446 [-0.0046, 0.0938]
		Moderate	0	0	0			
		Severe	0	0	0			
		Pain in extremity						
		Mild	0	3 (8.6%)	3 (2.9%)	0.1266 [0.0134, 1.1976]	0.1415 [0.0163, 1.2288] 0.0158	-0.0856 [-0.1783, 0.0072]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 94 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Arthritis reactive		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
	Musculoskeletal pain	Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Neck pain	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Back pain	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 95 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Neck mass		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pain in jaw	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Synovial cyst	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	4 (5.9%)	3 (8.6%)	7 (6.8%)			
		Moderate						
Skin and subcutaneous tissue disorders								
	Mild	4 (5.9%)	2 (5.7%)	6 (5.8%)	1.0924 [0.1879, 6.3513]	1.0855 [0.2119, 5.5618] 0.9224	0.0048 [-0.0899, 0.0995]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 96 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Rash	Moderate	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693]	-0.0293 [-0.0852, 0.0266]
		Severe	0	0	0		0.1489	
		Mild	2 (2.9%)	1 (2.9%)	3 (2.9%)	1.0422 [0.0954, 11.3916]	1.0414 [0.1034, 10.4874]	0.0012 [-0.0685, 0.0709]
	Urticaria	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.5%)	1 (2.9%)	2 (1.9%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
	Dermatitis allergic	Moderate	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693]	-0.0293 [-0.0852, 0.0266]
		Severe	0	0	0		0.1489	
		Mild	0	1 (2.9%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579]	-0.0269 [-0.0807, 0.0268]
		Severe	0	0	0		0.2008	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 97 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Dermatitis contact		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
	Cafe au lait spots	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Eczema	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Keratosis pilaris	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 98 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Petechiae		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pityriasis alba	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Rash erythematous	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Rash pruritic	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 99 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Immune system disorders	Mild		4 (5.9%)	2 (5.7%)	6 (5.8%)			
			4 (5.9%)	2 (5.7%)	6 (5.8%)	0.9565 [0.1626, 5.6256]	0.9600 [0.1888, 4.8807] 0.9610	-0.0023 [-0.0964, 0.0917]
			0	0	0			
	Moderate		0	0	0			
			0	0	0			
			0	0	0			
	Severe		2 (2.9%)	1 (2.9%)	3 (2.9%)			
			2 (2.9%)	1 (2.9%)	3 (2.9%)	0.9583 [0.0826, 11.1208]	0.9600 [0.0915, 10.0721] 0.9730	-0.0012 [-0.0692, 0.0668]
			0	0	0			
	Allergy to animal		2 (2.9%)	0	2 (1.9%)			
			2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515] 0.3239	0.0281 [-0.0113, 0.0676]
			0	0	0			
Hypersensitivity		0	1 (2.9%)	1 (1.0%)				
		0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]	
		0	0	0				
		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68) Genotropin n (N=35) Total (N=103)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>			
Investigations			5 (7.4%)	1 (2.9%)	6 (5.8%)			
		Mild	5 (7.4%)	1 (2.9%)	6 (5.8%)	2.6625 [0.3089, 22.9463]	2.5628 [0.3229, 20.3388] 0.3534	0.0458 [-0.0387, 0.1304]
		Moderate	0	0	0			
		Severe	0	0	0			
		Eosinophil count increased						
		Mild	2 (2.9%)	0	2 (1.9%)	1.7073 [0.1701, 17.1317]	1.6724 [0.1814, 15.4143] 0.2967	0.0305 [-0.0104, 0.0715]
		Moderate	0	0	0			
		Severe	0	0	0			
		Insulin-like growth factor increased						
		Mild	2 (2.9%)	0	2 (1.9%)	1.7073 [0.1701, 17.1317]	1.6724 [0.1814, 15.4143] 0.2967	0.0305 [-0.0104, 0.0715]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 101 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Blood iron increased		0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
		Moderate	0	0	0			
		Severe	0	0	0			
	White blood cell count decreased		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			
	Alanine aminotransferase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 102 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Aspartate aminotransferase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Blood cortisol decreased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Blood iron decreased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Blood thyroid stimulating hormone increased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 103 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Cortisol free urine decreased		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Thyroxine decreased	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Transaminases increased	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Blood and lymphatic system disorders		Severe	0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Mild	3 (4.4%)	2 (5.7%)	5 (4.9%)	0.7973	0.8014	-0.0116	
						[0.1345, 4.7252]	[0.1464, 4.3877]	[-0.1059, 0.0826]	
							0.7974		
Moderate	0	0	0						
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Blood and lymphatic system disorders	Anaemia		1 (1.5%)	1 (2.9%)	2 (1.9%)			
		Mild	1 (1.5%)	1 (2.9%)	2 (1.9%)	0.5614 [0.0377, 8.3605]	0.5614 [0.0413, 7.6362] 0.6603	-0.0129 [-0.0771, 0.0514]
		Moderate	0	0	0			
		Severe	0	0	0			
	Iron deficiency anaemia		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
		Severe	0	0	0			
	Lymphadenopathy		0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1551 [0.0061, 3.9520]	0.1634 [0.0069, 3.8693] 0.1489	-0.0293 [-0.0852, 0.0266]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 105 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Blood and lymphatic system disorders	Neutropenia		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			
Eye disorders			3 (4.4%)	0	3 (2.9%)			
		Mild	3 (4.4%)	0	3 (2.9%)	3.6105 [0.1792, 72.7389]	3.4314 [0.1843, 63.8959] 0.2237	0.0422 [-0.0057, 0.0902]
		Moderate	0	0	0			
	Astigmatism		0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 106 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Eye disorders	Eye haemorrhage		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
	Strabismus	Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
	Conjunctivitis allergic	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Eye swelling	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Hypermetropia	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 107 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Eye disorders	Myopia		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			3 (4.4%)	0	3 (2.9%)				
	Mild	3 (4.4%)	0	3 (2.9%)	2.2498 [0.2383, 21.2441]	2.1658 [0.2495, 18.8034] 0.2084	0.0446 [-0.0046, 0.0938]		
	Moderate	0	0	0					
	Severe	0	0	0					
	Skin papilloma			2 (2.9%)	0	2 (1.9%)			
		Mild	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515] 0.3239	0.0281 [-0.0113, 0.0676]	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 108 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
		Severe	0	0	0			
Psychiatric disorders			3 (4.4%)	0	3 (2.9%)			
		Mild	2 (2.9%)	0	2 (1.9%)	3.4848 [0.1526, 79.5782]	3.1579 [0.1654, 60.2804] 0.2602	0.0329 [-0.0095, 0.0754]
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 109 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Psychiatric disorders	Attention deficit/hyperactivity disorder		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
		Severe	0	0	0			
	Depressive symptom		1 (1.5%)	0	1 (1.0%)			
		Mild	0	0	0			
		Moderate	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
	Enuresis		0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0165 [-0.0138, 0.0468]
		Moderate	0	0	0			
		Severe	0	0	0			
	Affect lability		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 110 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Cardiac disorders			1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Sinoatrial block		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Tachycardia		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Sinus tachycardia		0	0	0				
	Mild	0	0	0					
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 111 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Ear and labyrinth disorders	Ear pain		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
			1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
			0	0	0			
	0	0	0					
Renal and urinary disorders			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 112 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Renal and urinary disorders	Pollakiuria		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236]	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0		0.4884	
	Polyuria	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Reproductive system and breast disorders	Severe	0	0	0			
			0	1 (2.9%)	1 (1.0%)			
		Mild	0	1 (2.9%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579]	-0.0269 [-0.0807, 0.0268]
Moderate		0	0	0		0.2008		
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 113 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Reproductive system and breast disorders	Genital discomfort		0	1 (2.9%)	1 (1.0%)				
		Mild	0	1 (2.9%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579] 0.2008	-0.0269 [-0.0807, 0.0268]	
		Moderate	0	0	0				
	Penile adhesion	Severe	0	0	0				
			0	1 (2.9%)	1 (1.0%)				
		Mild	0	1 (2.9%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579] 0.2008	-0.0269 [-0.0807, 0.0268]	
		Moderate	0	0	0				
	Vascular disorders		Severe	0	0	0			
				1 (1.5%)	0	1 (1.0%)			
		Mild		1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
Moderate			0	0	0				
Severe			0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 114 of 116



Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Vascular disorders	Hypotension		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.4848 [0.0583, 37.8008]	1.4706 [0.0621, 34.8236] 0.4884	0.0141 [-0.0140, 0.0422]
		Moderate	0	0	0			
		Severe	0	0	0			
Hepatobiliary disorders	Hepatomegaly		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
Metabolism and nutrition disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 115 of 116

Table 1.31 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by baseline GH-stimulation strata Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Metabolism and nutrition disorders	Polydipsia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 116 of 116

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=68)	Genotropi n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
Any adverse event			52 (76.5%)	26 (70.3%)	78 (74.3%)				
	Mild		32 (47.1%)	14 (37.8%)	46 (43.8%)	1.4465 [0.6380, 3.2795]	1.2368 [0.7617, 2.0083]	0.0897 [-0.1065, 0.2858]	0.6592
	Moderate		19 (27.9%)	12 (32.4%)	31 (29.5%)	0.8157 [0.3416, 1.9482]	0.8680 [0.4762, 1.5820]	-0.0427 [-0.2273, 0.1418]	0.1968
	Severe		1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
Infections and infestations			38 (55.9%)	23 (62.2%)	61 (58.1%)				
	Mild		25 (36.8%)	13 (35.1%)	38 (36.2%)	1.0629 [0.4598, 2.4570]	1.0397 [0.6087, 1.7757]	0.0140 [-0.1776, 0.2056]	0.3874
	Moderate		12 (17.6%)	10 (27.0%)	22 (21.0%)	0.5829 [0.2239, 1.5176]	0.6558 [0.3119, 1.3791]	-0.0925 [-0.2619, 0.0769]	0.9792
	Severe		1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon		Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			hGH (N=68)	Genotropin (N=37)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Nasopharyngitis		7 (10.3%)	7 (18.9%)	14 (13.3%)				
		Mild	6 (8.8%)	6 (16.2%)	12 (11.4%)	0.5016 [0.1505, 1.6717]	0.5440 [0.1898, 1.5589]	-0.0745 [-0.2119, 0.0629]	0.9987
		Moderate	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5512 [0.0328, 9.2482]	0.2561 0.5512 [0.0307, 9.8811]	-0.0116 [-0.0707, 0.0474]	1.0000
	Pharyngitis	Severe	0	0	0		0.6814		
		Mild	7 (10.3%)	5 (13.5%)	12 (11.4%)	0.7308 [0.2146, 2.4883]	0.7564 [0.2539, 2.2538]	-0.0327 [-0.1646, 0.0992]	0.9984
		Moderate	0	0	0		0.6180		0.9994
	Upper respiratory tract infection	Severe	0	0	0				
		Mild	5 (7.4%)	3 (8.1%)	8 (7.6%)				
		Mild	5 (7.4%)	1 (2.7%)	6 (5.7%)	2.8225 [0.3256, 24.4672]	2.7131 [0.3365, 21.8731]	0.0471 [-0.0351, 0.1292]	0.6030
							0.3263		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>				
Infections and infestations	Upper respiratory tract infection	Moderate	0	2 (5.4%)	2 (1.9%)	0.0970	0.1059	-0.0550	0.9994						
	Pharyngitis streptococcal	Severe	0	0	0										
		Mild	2 (2.9%)	4 (10.8%)	6 (5.7%)	0.2449	0.2600	-0.0407	0.9993						
	Ear infection	Moderate	1 (1.5%)	2 (5.4%)	3 (2.9%)	0.2449	0.2600	-0.0407	1.0000						
		Severe	0	0	0										
		Mild	5 (7.4%)	0	5 (4.8%)	1.6061	1.5882	0.0143	0.9973						
	Moderate	1 (1.5%)	0	1 (1.0%)	2.8618	2.7068	0.0587	0.9994							
	Severe	4 (5.9%)	0	4 (3.8%)											
	Severe	0	0	0											

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Sinusitis		3 (4.4%)	2 (5.4%)	5 (4.8%)				
		Mild	1 (1.5%)	2 (5.4%)	3 (2.9%)	0.2883 [0.0273, 3.0398]	0.2883 [0.0290, 2.8671]	-0.0391 [-0.1193, 0.0410]	1.0000
		Moderate	2 (2.9%)	0	2 (1.9%)	1.7766 [0.1772, 17.8149]	0.2560 1.7371 [0.1884, 16.0206]	0.0301 [-0.0105, 0.0708]	0.9993
	Gastroenteritis	Severe	0	0	0		0.2877		
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)				
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)	1.5957 [0.1577, 16.1502]	1.5600 [0.1706, 14.2632]	0.0154 [-0.0555, 0.0863]	0.9992
	Respiratory tract infection	Moderate	0	0	0				0.9990
		Severe	0	0	0				
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)				
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.1531 [0.1096, 12.1302]	1.1531 [0.1140, 11.6683]	0.0042 [-0.0640, 0.0724]	0.9598

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>				
Infections and infestations	Respiratory tract infection	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]						0.9979	
		Severe	0	0	0				0.4708						
		Rhinitis	2 (2.9%)	2 (5.4%)	4 (3.8%)										
	Bronchitis	Mild	2 (2.9%)	2 (5.4%)	4 (3.8%)	0.5565 [0.0720, 4.3035]	0.5811 [0.0849, 3.9772]	-0.0217 [-0.1027, 0.0593]						0.9992	
		Moderate	0	0	0										
		Severe	0	0	0										
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)										
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]						0.9998	
		Moderate	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5882 [0.0330, 10.4765]	0.6111 [0.0424, 8.8102]	-0.0101 [-0.0679, 0.0477]						0.9989	
	Severe	0	0	0				0.7202							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 5 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=37) Total (N=105)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Infections and infestations	Respiratory tract infection viral		2 (2.9%)	1 (2.7%)	3 (2.9%)				
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.1023 [0.0955, 12.7264]	1.1023 [0.0914, 13.2989] 0.9386	0.0027 [-0.0630, 0.0683]	0.9985
		Moderate Severe	0 0	0 0	0 0				0.9993
	Conjunctivitis		2 (2.9%)	0	2 (1.9%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate Severe	1 (1.5%) 0	0 0	1 (1.0%) 0	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997
	Enteritis infectious		0	2 (5.4%)	2 (1.9%)				
		Mild	0	0	0				0.9994
		Moderate Severe	0 0	2 (5.4%) 0	2 (1.9%) 0	0.1783 [0.0178, 1.7900]	0.1930 [0.0209, 1.7801] 0.0595	-0.0534 [-0.1259, 0.0191]	0.9994

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Gastroenteritis viral		2 (2.9%)	0	2 (1.9%)				
		Mild	2 (2.9%)	0	2 (1.9%)	1.7766 [0.1772, 17.8149]	1.7371 [0.1884, 16.0206] 0.2877	0.0301 [-0.0105, 0.0708]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Helminthic infection		1 (1.5%)	1 (2.7%)	2 (1.9%)				
		Mild	0	0	0				
		Moderate	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5102 [0.0306, 8.5029]	0.5200 [0.0339, 7.9810] 0.6356	-0.0132 [-0.0728, 0.0464]	1.0000
		Severe	0	0	0				
	Influenza		1 (1.5%)	1 (2.7%)	2 (1.9%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993
Moderate		1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Otitis media acute		1 (1.5%)	1 (2.7%)	2 (1.9%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.4708 0.1765 [0.0074, 4.1864]	-0.0275 [-0.0802, 0.0252]	0.9993
	Pharyngotonsillitis	Severe	0	0	0		0.1655		
		Mild	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864]	-0.0275 [-0.0802, 0.0252]	0.9993
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
	Tonsillitis	Severe	0	0	0		0.4708		
		Mild	1 (1.5%)	1 (2.7%)	2 (1.9%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0158 [-0.0138, 0.0455]	0.9997
		Moderate	1 (1.5%)	0	1 (1.0%)		0.4344		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 8 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Tonsillitis	Moderate	0	1 (2.7%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579]	-0.0259 [-0.0772, 0.0253]	0.9993
		Severe	0	0	0		0.2008		
	Viral infection	Mild	2 (2.9%)	0	2 (1.9%)	2.7320 [0.1264, 59.0317]	2.6471 [0.1317, 53.1845]	0.0286 [-0.0111, 0.0683]	1.0000
		Moderate	2 (2.9%)	0	2 (1.9%)		0.3046		0.9993
	Appendicitis	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)				
		Moderate	0	0	0				
		Severe	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
	Atypical pneumonia	Mild	1 (1.5%)	0	1 (1.0%)				
		Moderate	0	0	0				
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
		Severe	0	0	0		0.4708		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Conjunctivitis bacterial		0	1 (2.7%)	1 (1.0%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Cystitis		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Enterobiasis		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9979
		Moderate	0	0	0				
		Severe	0	0	0				
	Hordeolum		0	1 (2.7%)	1 (1.0%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993
Moderate		0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Infected bite		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
	Molluscum contagiosum	Severe	0	0	0				
			1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
	Otitis externa	Moderate	0	0	0				
		Severe	0	0	0				
			1 (1.5%)	0	1 (1.0%)				
	Pneumonia	Mild	0	0	0				
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Severe	0	0	0				
	Pneumonia	Mild	1 (1.5%)	0	1 (1.0%)				
			0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 11 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity				Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pneumonia	Moderate	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0158 [-0.0138, 0.0455]	0.9956
		Severe	0	0	0	0.4344			
	Pulpitis dental	Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0	0.4708			
	Tinea pedis	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
	Moderate	0	0	0	0.4708				
	Tooth abscess	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
	Moderate	0	0	0	0.4708				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Urinary tract infection		0	1 (2.7%)	1 (1.0%)				
		Mild	0	0	0				
		Moderate	0	1 (2.7%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579] 0.2008	-0.0259 [-0.0772, 0.0253]	0.9993
	Varicella	Severe	0	0	0				
		Mild	0	0	0				0.9994
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
	Viral upper respiratory tract infection	Severe	0	0	0				
		Mild	0	1 (2.7%)	1 (1.0%)				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 13 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity				Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Infections and infestations	Vulvitis		1 (1.5%)	0	1 (1.0%)					
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997	
		Moderate	0	0	0					
		Severe	0	0	0					
	Croup infectious			0	0	0				
		Mild	0	0	0					
		Moderate	0	0	0					
		Severe	0	0	0					
	Eczema infected			0	0	0				
		Mild	0	0	0				0.9994	
		Moderate	0	0	0					
		Severe	0	0	0					
	Laryngitis viral			0	0	0				
		Mild	0	0	0				0.9990	
		Moderate	0	0	0					
	Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 14 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Infections and infestations	Rotavirus infection		0	0	0				
		Mild	0	0	0				0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
Gastrointestinal disorders			18 (26.5%)	6 (16.2%)	24 (22.9%)				
		Mild	17 (25.0%)	4 (10.8%)	21 (20.0%)	2.7116 [0.8344, 8.8120]	2.2666 [0.8341, 6.1594]	0.1393 [-0.0043, 0.2828]	0.5763
		Moderate	1 (1.5%)	2 (5.4%)	3 (2.9%)	0.2449 [0.0211, 2.8369]	0.2600 [0.0247, 2.7350]	-0.0407 [-0.1190, 0.0377]	1.0000
		Severe	0	0	0		0.0894	0.2297	
	Vomiting	Mild	7 (10.3%)	3 (8.1%)	10 (9.5%)	1.9739 [0.3917, 9.9482]	1.8766 [0.4168, 8.4495]	0.0482 [-0.0551, 0.1515]	0.9995
		Moderate	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864]	-0.0275 [-0.0802, 0.0252]	0.9993
		Severe	0	0	0		0.4032	0.1655	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 15 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Gastrointestinal disorders	Diarrhoea		5 (7.4%)	3 (8.1%)	8 (7.6%)								
		Mild	5 (7.4%)	3 (8.1%)	8 (7.6%)	0.8756 [0.1970, 3.8907]	0.8855 [0.2280, 3.4391] 0.8618	-0.0094 [-0.1171, 0.0983]	0.9994				
		Moderate	0	0	0								
	Nausea		4 (5.9%)	2 (5.4%)	6 (5.7%)								
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)	1.5957 [0.1577, 16.1502]	1.5600 [0.1706, 14.2632] 0.6919	0.0154 [-0.0555, 0.0863]	1.0000				
		Moderate	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5102 [0.0306, 8.5029]	0.5200 [0.0339, 7.9810] 0.6356	-0.0132 [-0.0728, 0.0464]	1.0000				
	Abdominal pain upper		3 (4.4%)	1 (2.7%)	4 (3.8%)								
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)	1.5957 [0.1577, 16.1502]	1.5600 [0.1706, 14.2632] 0.6919	0.0154 [-0.0555, 0.0863]	1.0000				
		Moderate	0	0	0								
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 16 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Gastrointestinal disorders	Constipation		3 (4.4%)	0	3 (2.9%)					
		Mild	2 (2.9%)	0	2 (1.9%)	1.7766 [0.1772, 17.8149]	1.7371 [0.1884, 16.0206]	0.0301 [-0.0105, 0.0708]	0.9993	
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997	
	Abdominal pain	Severe	0	0	0		0.4708			
		Mild	2 (2.9%)	0	2 (1.9%)					
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9972	
	Abdominal discomfort	Severe	0	0	0		0.4708			
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997	
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997	
		Severe	0	0	0		0.4708			
			Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9998
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 17 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Aphthous ulcer			0	1 (2.7%)	1 (1.0%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864]	-0.0275 [-0.0802, 0.0252]	0.9993	
		Moderate	0	0	0		0.1655			
		Severe	0	0	0					
		Dyspepsia	Mild	1 (1.5%)	0	1 (1.0%)				
			Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0158 [-0.0138, 0.0455]	0.9998
			Moderate	0	0	0		0.4344		
		Severe	0	0	0					
		Gastric disorder	Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
			Moderate	0	0	0		0.4708		
			Severe	0	0	0				
		Toothache	Mild	1 (1.5%)	0	1 (1.0%)				
Mild	1 (1.5%)		0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9971		
Moderate	0		0	0		0.4708				
Severe	0	0	0							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 18 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Gastrointestinal disorders	Gastrointestinal motility disorder		0	0	0				
		Mild	0	0	0				0.9993
		Moderate	0	0	0				
	Lip swelling		0	0	0				
		Mild	0	0	0				0.9994
		Moderate	0	0	0				
Respiratory, thoracic and mediastinal disorders			18 (26.5%)	6 (16.2%)	24 (22.9%)				
	Mild	13 (19.1%)	5 (13.5%)	18 (17.1%)	1.5089 [0.4944, 4.6050]	1.4132 [0.5481, 3.6441]	0.0562 [-0.0890, 0.2013]	0.9781	
	Moderate	5 (7.4%)	1 (2.7%)	6 (5.7%)	2.8225 [0.3256, 24.4672]	2.7131 [0.3365, 21.8731]	0.0471 [-0.0351, 0.1292]	0.6594	
	Severe	0	0	0		0.4704 0.3263			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 19 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>										
Respiratory, thoracic and mediastinal disorders	Cough		4 (5.9%)	3 (8.1%)	7 (6.7%)										
		Mild	3 (4.4%)	2 (5.4%)	5 (4.8%)	0.8003 [0.1297, 4.9374]	0.8083 [0.1441, 4.5333]	-0.0105 [-0.0991, 0.0780]	0.9708						
		Moderate	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5766 [0.0377, 8.8058]	0.8099 0.5766 [0.0402, 8.2631]	-0.0116 [-0.0727, 0.0494]	1.0000						
	Asthma	Severe	0	0	0										
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997						
		Moderate	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5766 [0.0377, 8.8058]	0.4708 0.5766 [0.0402, 8.2631]	-0.0116 [-0.0727, 0.0494]	1.0000						
	Epistaxis	Severe	0	0	0										
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.0985 [0.0995, 12.1221]	1.0966 [0.1064, 11.3030]	0.0027 [-0.0643, 0.0696]	1.0000						
		Moderate	0	0	0										
		Severe	0	0	0										

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>				
Respiratory, thoracic and mediastinal disorders	Nasal congestion		2 (2.9%)	1 (2.7%)	3 (2.9%)										
		Mild	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5102 [0.0306, 8.5029]	0.5200 [0.0339, 7.9810]	-0.0132 [-0.0728, 0.0464]					1.0000		
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.6356	0.4708			0.9997		
	Respiratory disorder	Severe	0	0	0										
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	0.5766 [0.0377, 8.8058]	0.5766 [0.0402, 8.2631]	-0.0116 [-0.0727, 0.0494]					0.9994		
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.6814	0.4708			0.9971		
	Rhinitis allergic	Severe	0	0	0										
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.1023 [0.0955, 12.7264]	1.1023 [0.0914, 13.2989]	0.0027 [-0.0630, 0.0683]					1.0000		
		Moderate	0	0	0										
			Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=37) Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Respiratory, thoracic and mediastinal disorders	Sinus congestion		3 (4.4%)	0	3 (2.9%)				
		Mild	2 (2.9%)	0	2 (1.9%)	1.7766 [0.1772, 17.8149]	1.7371 [0.1884, 16.0206]	0.0301 [-0.0105, 0.0708]	0.9993
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
	Allergic cough	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
	Laryngospasm	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)				
		Moderate	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0158 [-0.0138, 0.0455]	0.9997
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		1 (1.5%)	0	1 (1.0%)				
		Mild	0	0	0				
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
	Rhinorrhoea	Severe	0	0	0				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9997
		Moderate	0	0	0				
	Sleep apnoea syndrome	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)				
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
	Wheezing	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)				0.9988

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 23 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Respiratory, thoracic and mediastinal disorders	Wheezing	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
		Severe	0	0	0				
	Dyspnoea exertional	Mild	0	0	0				
		Moderate	0	0	0				0.9994
		Severe	0	0	0				
		General disorders and administration site conditions		11 (16.2%)	7 (18.9%)	18 (17.1%)			
General disorders and administration site conditions	Mild	7 (10.3%)	7 (18.9%)	14 (13.3%)	0.4738 [0.1507, 1.4896]	0.5324 [0.2039, 1.3900]	-0.0893 [-0.2338, 0.0553]	0.9988	
	Moderate	4 (5.9%)	0	4 (3.8%)	5.1290 [0.2657, 99.0225]	4.7647 [0.2663, 85.2424]	0.0572 [0.0019, 0.1125]	0.9970	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 24 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=37) Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
General disorders and administration site conditions	Pyrexia		11 (16.2%)	5 (13.5%)	16 (15.2%)				
		Mild	7 (10.3%)	5 (13.5%)	12 (11.4%)	0.7173 [0.2093, 2.4582]	0.7478 [0.2557, 2.1870]	-0.0343 [-0.1655, 0.0970]	0.9991
		Moderate	4 (5.9%)	0	4 (3.8%)	5.1290 [0.2657, 99.0225]	4.7647 [0.2663, 85.2424]	0.0572 [0.0019, 0.1125]	0.9994
	Injection site swelling	Severe	0	0	0		0.5991		
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864]	-0.0275 [-0.0802, 0.0252]	0.9993
		Moderate	0	0	0		0.1655		
	Injection site urticaria	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0		0.4708		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and administrative site conditions	Medical device administration site	discomfort		0	1 (2.7%)	1 (1.0%)				
			Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993
			Moderate	0	0	0				
	Vaccination site	pain		0	1 (2.7%)	1 (1.0%)				
			Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993
			Moderate	0	0	0				
	Face	oedema		0	0	0				
			Mild	0	0	0				
			Moderate	0	0	0				0.9990
	Fatigue			0	0	0				
		Mild	0	0	0					0.9988
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 26 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
				TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
General disorders and administration site conditions	Gait disturbance			0	0	0				
		Mild	0	0	0				0.9994	
		Moderate	0	0	0					
	Influenza like illness			0	0	0				
		Mild	0	0	0					
		Moderate	0	0	0				0.9990	
	Injection site atrophy			0	0	0				
		Mild	0	0	0				0.9994	
		Moderate	0	0	0					
	Severe			0	0	0				
				0	0	0				
				0	0	0				
Nervous system disorders			10 (14.7%)	8 (21.6%)	18 (17.1%)					
	Mild	7 (10.3%)	6 (16.2%)	13 (12.4%)	0.5426 [0.1614, 1.8245]	0.6067 [0.2272, 1.6198]	-0.0649 [-0.2002, 0.0705]	0.9995		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Nervous system disorders	Headache	Moderate		3 (4.4%)	2 (5.4%)	5 (4.8%)	0.7660 [0.1198, 4.8984]	0.7800 [0.1389, 4.3791]	-0.0121 [-0.0991, 0.0749]	0.9987
			Severe	0	0	0		0.7791		
			Mild	9 (13.2%)	6 (16.2%)	15 (14.3%)	0.7500 [0.1916, 2.9360]	0.7800 [0.2414, 2.5208]	-0.0242 [-0.1425, 0.0941]	0.9992
		Dizziness	Moderate	3 (4.4%)	2 (5.4%)	5 (4.8%)	0.7660 [0.1198, 4.8984]	0.7800 [0.1389, 4.3791]	-0.0121 [-0.0991, 0.0749]	0.9987
			Severe	0	0	0		0.7791		
			Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.0417 [0.0900, 12.0549]	1.0400 [0.0989, 10.9401]	0.0011 [-0.0645, 0.0667]	1.0000
	Post-traumatic headache	Moderate	0	0	0		0.9741			
		Severe	0	0	0					
		Mild	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5102 [0.0306, 8.5029]	0.5200 [0.0339, 7.9810]	-0.0132 [-0.0728, 0.0464]	1.0000	
			Moderate	0	0	0		0.6356		
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Nervous system disorders	Migraine		0	1 (2.7%)	1 (1.0%)								
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993				
		Moderate	0	0	0								
	Tremor	Severe	0	0	0								
			0	0	0								
		Mild	0	0	0								
		Moderate	0	0	0				0.9994				
	Injury, poisoning and procedural complications	Severe	0	0	0								
			11 (16.2%)	3 (8.1%)	14 (13.3%)								
		Mild	7 (10.3%)	2 (5.4%)	9 (8.6%)	1.9639 [0.3830, 10.0710]	1.8483 [0.4118, 8.2962] 0.4141	0.0466 [-0.0554, 0.1487]	0.1980				
Moderate		4 (5.9%)	1 (2.7%)	5 (4.8%)	2.2091 [0.2394, 20.3827]	2.1366 [0.2529, 18.0502] 0.4758	0.0312 [-0.0456, 0.1081]	0.9997					
	Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 29 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>				
Injury, poisoning and bite procedural complications	Arthropod bite		1 (1.5%)	1 (2.7%)	2 (1.9%)										
		Mild	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5102 [0.0306, 8.5029]	0.5200 [0.0339, 7.9810]	-0.0132 [-0.0728, 0.0464]					1.0000		
		Moderate	0	0	0										
	Post-traumatic pain			1 (1.5%)	1 (2.7%)	2 (1.9%)									
		Mild	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5102 [0.0306, 8.5029]	0.5200 [0.0339, 7.9810]	-0.0132 [-0.0728, 0.0464]					1.0000		
		Moderate	0	0	0										
	Animal bite			1 (1.5%)	0	1 (1.0%)									
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]					0.9971		
		Moderate	0	0	0										
	Ankle fracture			1 (1.5%)	0	1 (1.0%)									
		Mild	0	0	0										

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Ankle fracture	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997	
		Severe	0	0	0	0.4708				
		Burns second degree	1 (1.5%)	0	1 (1.0%)					
	Contusion	Mild	0	0	0					
		Moderate	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0158 [-0.0138, 0.0455]	0.9997	
		Severe	0	0	0	0.4344				
	Face injury	Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0158 [-0.0138, 0.0455]	0.9997	
		Moderate	0	0	0					
		Severe	0	0	0					
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997	
		Moderate	0	0	0	0.4708				
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Fall		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997
		Moderate	0	0	0				
	Head injury	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
	Laceration	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=68)		Genotropin n (N=37)		Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>						
Injury, poisoning and procedural complications	Ligament sprain			1 (1.5%)	0	1 (1.0%)						
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997			
		Moderate	0	0	0							
	Meniscus injury				0	1 (2.7%)	1 (1.0%)					
		Mild	0	0	0							
		Moderate	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993			
	Muscle strain				0	0	0					
		Mild	0	0	0							
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997			
					0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Injury, poisoning and procedural complications	Thermal burn		0	1 (2.7%)	1 (1.0%)					
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993	
		Moderate	0	0	0					
		Wrist fracture	Severe	0	0	0				
			Mild	1 (1.5%)	0	1 (1.0%)				
			Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Burns first degree	Moderate	0	0	0				
			Severe	0	0	0				
			Mild	0	0	0				0.9990
		Concussion	Moderate	0	0	0				
			Severe	0	0	0				
			Mild	0	0	0				0.9990
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 34 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value	
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)					
Injury, poisoning and procedural complications	Radius fracture		0	0	0				0.9994	
		Mild	0	0	0					
		Moderate	0	0	0					
	Upper limb fracture	Severe	0	0	0				0.9993	
		Mild	0	0	0					
		Moderate	0	0	0					
	Musculoskeletal and connective tissue disorders		Severe	0	0	0				
			Mild	8 (11.8%)	6 (16.2%)	14 (13.3%)				
			Moderate	2 (2.9%)	0	2 (1.9%)	2.7320 [0.1264, 59.0317]	2.6471 [0.1317, 53.1845]	0.0286 [-0.0111, 0.0683]	0.9993
Severe			0	0	0		0.3046			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>										
Musculoskeletal and connective tissue disorders	Pain in extremity		3 (4.4%)	4 (10.8%)	7 (6.7%)										
		Mild	2 (2.9%)	4 (10.8%)	6 (5.7%)	0.2406 [0.0411, 1.4083]	0.2637 [0.0499, 1.3947]	-0.0798 [-0.1874, 0.0278]	0.9994						
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997						
		Severe	0	0	0		0.0940	0.4708							
	Arthralgia		4 (5.9%)	1 (2.7%)	5 (4.8%)										
		Mild	4 (5.9%)	1 (2.7%)	5 (4.8%)	2.2091 [0.2394, 20.3827]	2.1366 [0.2529, 18.0502]	0.0312 [-0.0456, 0.1081]	0.9997						
		Moderate	0	0	0		0.4758								
		Severe	0	0	0										
	Musculoskeletal pain		2 (2.9%)	0	2 (1.9%)										
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 36 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>				
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061	1.5882	0.0143	0.9997						
	Neck pain	Severe	0	0	0										
		Mild	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5102	0.5200	-0.0132	1.0000						
	Arthritis reactive	Moderate	0	0	0										
		Severe	0	0	0										
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061	1.5882	0.0143	0.9997						
	Back pain	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061	1.5882	0.0143	0.9997						
		Mild	0	0	0										
		Severe	0	0	0										

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Neck mass		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
	Pain in jaw	Severe	0	0	0				
			1 (1.5%)	0	1 (1.0%)				
		Mild	0	0	0				
	Synovial cyst	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Severe	0	0	0				
			0	1 (2.7%)	1 (1.0%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579] 0.2008	-0.0259 [-0.0772, 0.0253]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 38 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=37) Total (N=105)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Skin and subcutaneous tissue disorders			7 (10.3%)	2 (5.4%)	9 (8.6%)				
		Mild	6 (8.8%)	2 (5.4%)	8 (7.6%)	1.7333 [0.3286, 9.1437]	1.6636 [0.3516, 7.8708] 0.5178	0.0355 [-0.0634, 0.1344]	0.9990
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9977
		Severe	0	0	0				
		Rash							
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)	1.6422 [0.1675, 16.1029]	1.6166 [0.1785, 14.6398] 0.6677	0.0169 [-0.0552, 0.0891]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
		Cafe au lait spots							
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 39 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)			Genotropin n (N=37)			Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>										
Skin and subcutaneous tissue disorders	Dermatitis allergic		0	1 (2.7%)	1 (1.0%)										
		Mild	0	1 (2.7%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579] 0.2008	-0.0259 [-0.0772, 0.0253]	0.9993						
		Moderate	0	0	0										
	Eczema	Severe	0	0	0										
		Mild	1 (1.5%)	0	1 (1.0%)										
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997						
	Keratosis pilaris	Severe	0	0	0										
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997						
		Moderate	0	0	0										
			Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 40 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Pityriasis alba		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997
		Moderate	0	0	0				
	Rash erythematous	Severe	0	0	0				
			1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
	Urticaria	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				0.9990
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 41 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value	
			TransCon hGH (N=68)	Genotropin (N=37)	Total (N=105)					
Skin and subcutaneous tissue disorders	Dermatitis contact		0	0	0				0.9994	
		Mild	0	0	0					
		Moderate	0	0	0					
	Petechiae		0	0	0				0.9993	
		Mild	0	0	0					
		Moderate	0	0	0					
	Rash pruritic		0	0	0				0.9990	
		Mild	0	0	0					
		Moderate	0	0	0					
	Immune system disorders			6 (8.8%)	2 (5.4%)	8 (7.6%)				
		Mild	5 (7.4%)	2 (5.4%)	7 (6.7%)	1.3333 [0.2404, 7.3943]	1.3000 [0.2705, 6.2477]	0.0165 [-0.0779, 0.1109]	0.9996	
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997	
Severe		0	0	0		0.4708				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Immune system disorders	Seasonal allergy		3 (4.4%)	1 (2.7%)	4 (3.8%)				
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)	1.5957 [0.1577, 16.1502]	1.5600 [0.1706, 14.2632] 0.6919	0.0154 [-0.0555, 0.0863]	0.9997
		Moderate	0	0	0				
	Allergy to animal	Severe	0	0	0				
			2 (2.9%)	0	2 (1.9%)				
		Mild	2 (2.9%)	0	2 (1.9%)	2.7320 [0.1264, 59.0317]	2.6471 [0.1317, 53.1845] 0.3046	0.0286 [-0.0111, 0.0683]	0.9993
	Hypersensitivity	Moderate	0	0	0				
		Severe	0	0	0				
			1 (1.5%)	1 (2.7%)	2 (1.9%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 43 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=37) Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Investigations			6 (8.8%)	1 (2.7%)	7 (6.7%)				
		Mild	6 (8.8%)	1 (2.7%)	7 (6.7%)	3.4273 [0.4035, 29.1108]	3.2331 [0.4127, 25.3283] 0.2333	0.0614 [-0.0246, 0.1474]	0.4278
		Moderate	0	0	0				
		Severe	0	0	0				
	Eosinophil count increased		2 (2.9%)	0	2 (1.9%)				
		Mild	2 (2.9%)	0	2 (1.9%)	1.7766 [0.1772, 17.8149]	1.7371 [0.1884, 16.0206] 0.2877	0.0301 [-0.0105, 0.0708]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Insulin-like growth factor increased		2 (2.9%)	0	2 (1.9%)				
		Mild	2 (2.9%)	0	2 (1.9%)	1.7766 [0.1772, 17.8149]	1.7371 [0.1884, 16.0206] 0.2877	0.0301 [-0.0105, 0.0708]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Blood iron increased			0	1 (2.7%)	1 (1.0%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864] 0.1655	-0.0275 [-0.0802, 0.0252]	0.9993	
		Moderate	0	0	0					
		Severe	0	0	0					
	Blood thyroid stimulating hormone increased			1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
		Moderate	0	0	0					
		Severe	0	0	0					
	White blood cell count decreased			1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 45 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Investigations	Alanine aminotransferase increased		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Aspartate aminotransferase increased		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood cortisol decreased		0	0	0				
		Mild	0	0	0				0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood iron decreased		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
Severe		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 46 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
				TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Investigations	Cortisol free urine decreased			0	0	0				
		Mild	0	0	0				0.9993	
		Moderate	0	0	0					
	Thyroxine decreased	Severe	0	0	0					
		Mild	0	0	0				0.9990	
		Moderate	0	0	0					
	Transaminases increased	Severe	0	0	0					
		Mild	0	0	0				0.9994	
		Moderate	0	0	0					
	Endocrine disorders			2 (2.9%)	3 (8.1%)	5 (4.8%)				
		Mild	1 (1.5%)	3 (8.1%)	4 (3.8%)	0.1813 [0.0182, 1.8039]	0.1959 [0.0227, 1.6870]	-0.0651 [-0.1577, 0.0276]	0.1004	0.4122

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 47 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Secondary hypothyroidism	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9998
		Severe	0	0	0				
	Mild	2 (2.9%)	3 (8.1%)	5 (4.8%)					
	Moderate	1 (1.5%)	3 (8.1%)	4 (3.8%)	0.1813 [0.0182, 1.8039]	0.1959 [0.0227, 1.6870]	-0.0651 [-0.1577, 0.0276]	0.9984	
	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
	Severe	0	0	0					
	Adrenal insufficiency	0	0	0					
	Mild	0	0	0					
	Moderate	0	0	0				0.9994	
	Severe	0	0	0					
Diabetes insipidus	0	0	0						
Mild	0	0	0				1.0000		
Moderate	0	0	0						
Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 48 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)				
Endocrine disorders	Hypothyroidism		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Secondary adrenocortical insufficiency		0	0	0				
		Mild	0	0	0				1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood and lymphatic system disorders			3 (4.4%)	1 (2.7%)	4 (3.8%)			
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.0985 [0.0995, 12.1221]	1.0966 [0.1064, 11.3030]	0.0027 [-0.0643, 0.0696]	0.9316
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9998
		Severe	0	0	0		0.4708		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 49 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders	Lymphadenopathy		1 (1.5%)	1 (2.7%)	2 (1.9%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1683 [0.0066, 4.2799]	0.1765 [0.0074, 4.1864]	-0.0275 [-0.0802, 0.0252]	0.9993
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9997
	Anaemia	Severe	0	0	0		0.1655 0.4708		
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209]	0.0158 [-0.0138, 0.0455]	0.9971
		Moderate	0	0	0				
	Neutropenia	Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772]	0.0143 [-0.0140, 0.0425]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 50 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=37) Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Blood and lymphatic system disorders	Iron deficiency anaemia		0	0	0				
		Mild	0	0	0				0.9995
		Moderate	0	0	0				0.9993
		Severe	0	0	0				
Eye disorders			4 (5.9%)	0	4 (3.8%)				
		Mild	4 (5.9%)	0	4 (3.8%)	2.8618 [0.3121, 26.2432]	2.7068 [0.3205, 22.8620] 0.1368	0.0587 [0.0028, 0.1147]	0.9968
		Moderate	0	0	0				
		Severe	0	0	0				
	Conjunctivitis allergic		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value	
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Eye disorders	Eye	haemorrhage		1 (1.5%)	0	1 (1.0%)					
			Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
			Moderate	0	0	0					
			Severe	0	0	0					
			Eye swelling	Mild	1 (1.5%)	0	1 (1.0%)				
				Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997
				Moderate	0	0	0				
				Severe	0	0	0				
			Strabismus	Mild	1 (1.5%)	0	1 (1.0%)				
				Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9973
				Moderate	0	0	0				
				Severe	0	0	0				
			Astigmatism	Mild	0	0	0				
				Moderate	0	0	0				
Severe	0	0		0							
Severe	0	0		0				0.9994			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 52 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH vs. Genotropin			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			(N=68)	(N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Eye disorders	Hypermetropia		0	0	0				0.9993
		Mild	0	0	0				
		Moderate	0	0	0				
	Myopia	Severe	0	0	0				0.9990
			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Severe	0	0	0				
			3 (4.4%)	1 (2.7%)	4 (3.8%)				
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)	1.6422 [0.1675, 16.1029]	1.6166 [0.1785, 14.6398] 0.6677	0.0169 [-0.0552, 0.0891]	
	Skin papilloma	Moderate	0	0	0				
		Severe	0	0	0				
			2 (2.9%)	1 (2.7%)	3 (2.9%)				
		Mild	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.0417 [0.0900, 12.0549]	1.0400 [0.0989, 10.9401] 0.9741	0.0011 [-0.0645, 0.0667]	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 53 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=37) Total (N=105)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
Psychiatric disorders			3 (4.4%)	1 (2.7%)	4 (3.8%)				
		Mild	3 (4.4%)	1 (2.7%)	4 (3.8%)	1.6868 [0.1787, 15.9187]	1.6731 [0.1864, 15.0171] 0.6403	0.0185 [-0.0548, 0.0918]	1.0000
		Moderate	0	0	0				0.9994
	Attention deficit/hyperactivity disorder		1 (1.5%)	1 (2.7%)	2 (1.9%)				
		Mild	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5766 [0.0377, 8.8058]	0.5766 [0.0402, 8.2631] 0.6814	-0.0116 [-0.0727, 0.0494]	1.0000
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 54 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Psychiatric disorders	Affect lability			1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
		Moderate	0	0	0					
		Severe	0	0	0					
		Enuresis	Mild	1 (1.5%)	0	1 (1.0%)				
			Mild	1 (1.5%)	0	1 (1.0%)	1.9714 [0.0737, 52.7047]	1.8947 [0.0838, 42.8209] 0.4344	0.0158 [-0.0138, 0.0455]	0.9997
	Depressive symptom	Moderate	0	0	0					
		Severe	0	0	0					
			0	0	0					
		Mild	0	0	0					
		Moderate	0	0	0				0.9994	
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 55 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=68) Genotropin (N=37) Total (N=105)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Ear and labyrinth disorders	Ear pain		3 (4.4%)	0	3 (2.9%)				
		Mild	3 (4.4%)	0	3 (2.9%)	2.3462 [0.2487, 22.1374]	2.2540 [0.2594, 19.5823] 0.1970	0.0444 [-0.0046, 0.0935]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	3 (4.4%)	0	3 (2.9%)	2.3462 [0.2487, 22.1374]	2.2540 [0.2594, 19.5823] 0.1970	0.0444 [-0.0046, 0.0935]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
Cardiac disorders			2 (2.9%)	0	2 (1.9%)				
	Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
	Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 56 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Cardiac disorders	Sinoatrial block			1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
		Moderate	0	0	0					
		Severe	0	0	0					
			1 (1.5%)	0	1 (1.0%)					
			0	0	0					
	Sinus tachycardia	Mild	0	0	0					
		Moderate	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
		Severe	0	0	0					
			1 (1.5%)	0	1 (1.0%)					
			1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997	
			0	0	0					
Tachycardia	Mild	1 (1.5%)	0	1 (1.0%)						
	Moderate	0	0	0						
	Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 57 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Renal and urinary disorders			2 (2.9%)	0	2 (1.9%)				
		Mild	2 (2.9%)	0	2 (1.9%)	2.7320 [0.1264, 59.0317]	2.6471 [0.1317, 53.1845] 0.3046	0.0286 [-0.0111, 0.0683]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
		Pollakiuria							
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
		Polyuria							
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 58 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Reproductive system and breast disorders	Penile adhesion		0	2 (5.4%)	2 (1.9%)				
		Mild	0	2 (5.4%)	2 (1.9%)	0.1783 [0.0178, 1.7900]	0.1930 [0.0209, 1.7801] 0.0595	-0.0534 [-0.1259, 0.0191]	0.9994
		Moderate	0	0	0				
		Severe	0	0	0				
			0	2 (5.4%)	2 (1.9%)				
		Mild	0	2 (5.4%)	2 (1.9%)	0.1783 [0.0178, 1.7900]	0.1930 [0.0209, 1.7801] 0.0595	-0.0534 [-0.1259, 0.0191]	0.9994
	Genital discomfort	Moderate	0	0	0				
		Severe	0	0	0				
			0	1 (2.7%)	1 (1.0%)				
		Mild	0	1 (2.7%)	1 (1.0%)	0.1892 [0.0071, 5.0732]	0.2105 [0.0093, 4.7579] 0.2008	-0.0259 [-0.0772, 0.0253]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 59 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Metabolism and nutrition disorders	Polydipsia		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
			1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9998
		Moderate	0	0	0				
Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 60 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated idiopathic

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=68)	Genotropin n (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Vascular disorders		Hypotension		1 (1.5%)	0	1 (1.0%)				
			Mild	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9998
			Moderate	0	0	0				
			Severe	0	0	0				
Hepatobiliary disorders		Hepatomegaly		0	0	0				
			Mild	0	0	0				0.9990
			Moderate	0	0	0				
			Severe	0	0	0				
			Mild	0	0	0				0.9990
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 61 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)						Lonapegsomatropin vs. Genotropina <sup>a</sup>		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Any adverse event			15 (78.9%)	4 (44.4%)	19 (67.9%)			
		Mild	11 (57.9%)	3 (33.3%)	14 (50.0%)	2.2857 [0.4103, 12.7323]	1.6000 [0.5666, 4.5184]	0.2000 [-0.1982, 0.5982]
		Moderate	4 (21.1%)	1 (11.1%)	5 (17.9%)	2.0000 [0.1754, 22.7989]	1.8000 [0.2189, 14.8009]	0.0889 [-0.1994, 0.3772]
		Severe	0	0	0		0.3514	
Infections and infestations			10 (52.6%)	2 (22.2%)	12 (42.9%)			
		Mild	9 (47.4%)	2 (22.2%)	11 (39.3%)	2.3333 [0.3558, 15.3004]	1.8000 [0.4572, 7.0866]	0.1778 [-0.1900, 0.5455]
		Moderate	1 (5.3%)	0	1 (3.6%)		0.3813	0.0000 [0.0000, 0.0000]
		Severe	0	0	0			
		Nasopharyngitis	5 (26.3%)	0	5 (17.9%)			
		Mild	5 (26.3%)	0	5 (17.9%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826]	0.2000 [-0.0024, 0.4024]
	Moderate	0	0	0		0.1603		
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 62 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Pharyngitis		3 (15.8%)	0	3 (10.7%)			
		Mild	2 (10.5%)	0	2 (7.1%)			0.0000 [0.0000, 0.0000]
		Moderate	1 (5.3%)	0	1 (3.6%)			0.0000 [0.0000, 0.0000]
	Upper respiratory tract infection	Severe	0	0	0			
		Mild	1 (5.3%)	1 (11.1%)	2 (7.1%)			
		Mild	1 (5.3%)	1 (11.1%)	2 (7.1%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0444 [-0.2855, 0.1966]
	Viral infection	Severe	0	0	0			
		Mild	2 (10.5%)	0	2 (7.1%)			
		Mild	2 (10.5%)	0	2 (7.1%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 63 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Croup infectious		0	1 (11.1%)	1 (3.6%)			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Ear infection		0	1 (11.1%)	1 (3.6%)			
		Mild	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318]	-0.1111 [-0.3164, 0.0942]
		Moderate	0	0	0		0.1967	
	Eczema infected		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)			0.0000 [0.0000, 0.0000]
		Moderate	0	0	0			
	Enteritis infectious		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0667 [-0.0596, 0.1929]
		Moderate	0	0	0		0.4386	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 64 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>
							[95 %-CI] <sup>b</sup>	
Infections and infestations	Gastroenteritis viral		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Moderate	0	0	0			
	Pharyngitis streptococcal	Severe	0	0	0			
			1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
	Rhinitis	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
	Varicella	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 65 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Viral upper respiratory tract infection		1 (5.3%)	0	1 (3.6%)				
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Appendicitis			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Atypical pneumonia			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Bronchitis			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
	Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 66 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Conjunctivitis		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Conjunctivitis bacterial			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Cystitis			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Enterobiasis			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Gastroenteritis			0	0	0			
		Mild		0	0	0			
Moderate			0	0	0				
	Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 67 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=9)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Infections and infestations	Helminthic infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hordeolum		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Infected bite		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Influenza		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Laryngitis viral		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 68 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=19)	
Infections and infestations	Molluscum contagiosum		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis externa		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis media acute		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngotonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pneumonia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 69 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
			(N=19)	(N=9)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>	
Infections and infestations	Pulpitis dental		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
	Respiratory tract infection	Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
	Respiratory tract infection viral	Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
Rotavirus infection	Severe		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Severe		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=9)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Infections and infestations	Sinusitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tinea pedis	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tonsillitis	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tooth abscess	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Urinary tract infection	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 71 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Vulvitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
General disorders and administration site conditions	Pyrexia		6 (31.6%)	0	6 (21.4%)			
		Mild	6 (31.6%)	0	6 (21.4%)	7.4348 [0.3537, 156.2808]	5.6250 [0.3377, 93.7010] 0.0966	0.2667 [0.0429, 0.4905]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	4 (21.1%)	0	4 (14.3%)			
		Mild	4 (21.1%)	0	4 (14.3%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826] 0.1603	0.2000 [-0.0024, 0.4024]
		Moderate	0	0	0			
Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions	Fatigue		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Moderate	0	0	0			
	Gait disturbance	Severe	0	0	0			
			1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)			0.0000 [0.0000, 0.0000]
	Injection site atrophy	Moderate	0	0	0			
		Severe	0	0	0			
			1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 73 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=9)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
General disorders and administration site conditions	Face oedema		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Influenza like illness	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Injection site swelling	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Injection site urticaria	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 74 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and device administration site conditions	Medical		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Vaccination site pain	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Respiratory, thoracic and mediastinal disorders			6 (31.6%)	0	6 (21.4%)		
Mild		5 (26.3%)	0	5 (17.9%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826]	0.2000 [-0.0024, 0.4024]	
Moderate		1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0667 [-0.0596, 0.1929]	
Severe		0	0	0		0.4386		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 75 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)					Lonapegsomatropin vs. Genotropina <sup>a</sup>			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Cough		5 (26.3%)	0	5 (17.9%)			
		Mild	5 (26.3%)	0	5 (17.9%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826] 0.1603	0.2000 [-0.0024, 0.4024]
		Moderate	0	0	0			
	Dyspnoea exertional	Severe	0	0	0			
			1 (5.3%)	0	1 (3.6%)			
		Mild	0	0	0			
	Wheezing	Moderate	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Severe	0	0	0			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
	Allergic cough	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=9)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Asthma		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Epistaxis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Laryngospasm		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal congestion		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Paranasal sinus discomfort		0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 77 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rhinitis allergic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rhinorrhoea		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinus congestion		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sleep apnoea syndrome		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 78 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)					Lonapegsomatropin vs. Genotropina <sup>a</sup>			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders			4 (21.1%)	0	4 (14.3%)			
		Mild	3 (15.8%)	0	3 (10.7%)	3.5185 [0.1511, 81.9250]	3.1250 [0.1666, 58.6274] 0.2627	0.1333 [-0.0387, 0.3054]
		Moderate	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Severe	0	0	0			
	Headache		4 (21.1%)	0	4 (14.3%)			
		Mild	3 (15.8%)	0	3 (10.7%)	3.5185 [0.1511, 81.9250]	3.1250 [0.1666, 58.6274] 0.2627	0.1333 [-0.0387, 0.3054]
		Moderate	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Severe	0	0	0			
	Tremor		1 (5.3%)	0	1 (3.6%)			
		Mild	0	0	0			
		Moderate	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=19)		(N=9)
Nervous system disorders	Dizziness		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Migraine	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Post-traumatic headache	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Eye disorders	Severe		0	0	0			
			Mild	1 (5.3%)	2 (22.2%)	3 (10.7%)	0.2500	0.3000	-0.1556
			Moderate	1 (5.3%)	2 (22.2%)	3 (10.7%)	[0.0192, 3.2541]	[0.0315, 2.8569]	[-0.4551, 0.1440]
Severe			0	0	0		0.2748		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)						Lonapegsomatropin vs. Genotropina <sup>a</sup>		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>
							[95 %-CI] <sup>b</sup>	
Eye disorders	Astigmatism	Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Moderate	0	0	0			
		Severe	0	0	0			
	Myopia	Mild	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.1111 [-0.3164, 0.0942]
		Moderate	0	0	0			
		Severe	0	0	0			
	Strabismus	Mild	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.1111 [-0.3164, 0.0942]
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis allergic	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 81 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=19)	
Eye disorders	Eye haemorrhage		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye swelling		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypermetropia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Gastrointestinal disorders			3 (15.8%)	0	3 (10.7%)			
		Mild	3 (15.8%)	0	3 (10.7%)	3.5185	3.1250	0.1333
						[0.1511, 81.9250]	[0.1666, 58.6274]	[-0.0387, 0.3054]
		Moderate	0	0	0		0.2627	
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 82 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Abdominal discomfort		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal pain		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Moderate	0	0	0			
		Severe	0	0	0			
	Lip swelling		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)			0.0000 [0.0000, 0.0000]
		Moderate	0	0	0			
		Severe	0	0	0			
Vomiting		1 (5.3%)	0	1 (3.6%)				
	Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 83 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
			(N=19)	(N=9)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Abdominal pain upper		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Aphthous ulcer			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Constipation			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Diarrhoea			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Dyspepsia			0	0	0			
		Mild		0	0	0			
Moderate			0	0	0				
	Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 84 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>	
							[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
Gastrointestinal disorders	Gastric disorder		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal motility disorder			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Nausea			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Toothache			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
	Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 85 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)						Lonapegsomatropin vs. Genotropina <sup>a</sup>			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders			2 (10.5%)	0	2 (7.1%)				
		Mild	2 (10.5%)	0	2 (7.1%)	3.5185 [0.1511, 81.9250]	3.1250 [0.1666, 58.6274] 0.2627	0.1333 [-0.0387, 0.3054]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Iron deficiency anaemia		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Neutropenia		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 86 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)					Lonapegsomatropin vs. Genotropina <sup>a</sup>				
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	RR		RD [95 %-CI] <sup>b</sup>	
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>		
Blood and lymphatic system disorders	Anaemia		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Lymphadenopathy		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Injury, poisoning and procedural complications			2 (10.5%)	0	2 (7.1%)			
		Mild		1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
Moderate			1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
Severe			0	0	0				
Contusion			1 (5.3%)	0	1 (3.6%)				
		Mild	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 87 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Contusion	Moderate	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0667 [-0.0596, 0.1929]
		Severe	0	0	0	0.4386		
		Radius fracture	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0667 [-0.0596, 0.1929]
	Animal bite	Mild	1 (5.3%)	0	1 (3.6%)	0.4386		
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Ankle fracture	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and bite procedural complications	Arthropod		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Burns first degree	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Burns second degree	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Concussion	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Face injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 89 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=19)		(N=9)
Injury, poisoning and procedural complications	Fall		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Head injury	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Laceration	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Ligament sprain	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Meniscus injury	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 90 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=19)	
Injury, poisoning and procedural complications	Muscle strain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Post-traumatic pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thermal burn		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Upper limb fracture		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Wrist fracture		0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 91 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations			1 (5.3%)	1 (11.1%)	2 (7.1%)				
		Mild	1 (5.3%)	1 (11.1%)	2 (7.1%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0444 [-0.2855, 0.1966]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Blood iron decreased		0	1 (11.1%)	1 (3.6%)			
		Mild	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.1111 [-0.3164, 0.0942]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Thyroxine decreased		0	1 (11.1%)	1 (3.6%)			
		Mild	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.1111 [-0.3164, 0.0942]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Transaminases increased		1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Alanine aminotransferase increased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Aspartate aminotransferase increased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood cortisol decreased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood iron increased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 93 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=19)	
Investigations	Blood thyroid stimulating hormone increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cortisol free urine decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eosinophil count increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Insulin-like growth factor increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 94 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>							
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Investigations	White blood cell counts decreased		0	0	0					
		Mild	0	0	0					
		Moderate	0	0	0					
		Severe	0	0	0					
Skin and subcutaneous tissue disorders	Dermatitis contact		1 (5.3%)	1 (11.1%)	2 (7.1%)					
		Mild	1 (5.3%)	0	1 (3.6%)			0.0000 [0.0000, 0.0000]		
		Moderate	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318]	-0.1111 [-0.3164, 0.0942]		
		Severe	0	0	0		0.1967			
		Mild	1 (5.3%)	0	1 (3.6%)			0.0000 [0.0000, 0.0000]		
		Moderate	0	0	0					
		Severe	0	0	0					
		Rash pruritic	Mild		0	1 (11.1%)	1 (3.6%)			
					0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318]	-0.1111 [-0.3164, 0.0942]
		Severe	0	0	0			
	Cafe au lait spots	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		0.1967						
	Dermatitis allergic	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eczema	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Keratosis pilaris	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 96 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=19)	
Skin and subcutaneous tissue disorders	Petechiae		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pityriasis alba	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Rash	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Rash erythematous	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 97 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	RR			
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Ear and labyrinth disorders			1 (5.3%)	0	1 (3.6%)				
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Ear pain		1 (5.3%)	0	1 (3.6%)				
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Endocrine disorders			1 (5.3%)	0	1 (3.6%)			
			Mild	0	0	0			
		Moderate	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
		Severe	0	0	0				
Adrenal insufficiency			1 (5.3%)	0	1 (3.6%)				
	Mild	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 98 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)						Lonapegsomatropin vs. Genotropina <sup>a</sup>		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR	RD
							[95 %-CI] <sup>b</sup>	p-value <sup>c</sup>
Endocrine disorders	Adrenal insufficiency	Moderate	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0667 [-0.0596, 0.1929]
		Severe	0	0	0		0.4386	
	Diabetes insipidus	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypothyroidism	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Secondary adrenocortical insufficiency	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Secondary hypothyroidism	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 99 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)						Lonapegsomatropin vs. Genotropina <sup>a</sup>			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Hepatobiliary disorders	Hepatomegaly		0	1 (11.1%)	1 (3.6%)				
		Mild	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.1111 [-0.3164, 0.0942]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	0	1 (11.1%)	1 (3.6%)				
		Mild	0	1 (11.1%)	1 (3.6%)	0.1828 [0.0067, 4.9965]	0.2083 [0.0094, 4.6318] 0.1967	-0.1111 [-0.3164, 0.0942]	
	Immune system disorders			1 (5.3%)	0	1 (3.6%)			
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Seasonal allergy	1 (5.3%)	0	1 (3.6%)				
		Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropi n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Immune system disorders	Allergy to animal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Hypersensitivity	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Musculoskeletal and connective tissue disorders			1 (5.3%)	0	1 (3.6%)			
	Mild		1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0667 [-0.0596, 0.1929]
		Moderate	0	0	0		0.4386	
		Severe	0	0	0			
	Arthralgia	Mild	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0667 [-0.0596, 0.1929]
		Mild	1 (5.3%)	0	1 (3.6%)		0.4386	
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=19)	(N=9)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Arthritis reactive		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Back pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Musculoskeletal pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck mass	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 102 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Pain in extremity		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pain in jaw	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Synovial cyst	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Psychiatric disorders	Severe	0	0	0			
			1 (5.3%)	0	1 (3.6%)			
		Mild	0	0	0			
Moderate		1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860]	0.0667 [-0.0596, 0.1929]	
	Severe	0	0	0		0.4386		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=19)	Genotropin n (N=9)	Total (N=28)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Psychiatric disorders	Depressive symptom		1 (5.3%)	0	1 (3.6%)			
		Mild	0	0	0			
		Moderate	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]
		Severe	0	0	0			
	Affect lability		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Attention deficit/hyperactivity disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Enuresis		0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 104 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=19)	
Cardiac disorders		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinoatrial block		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Sinus tachycardia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tachycardia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Metabolism and nutrition disorders		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
Severe		0	0	0				
		0	0	0				
		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 105 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=19)		(N=9)
Metabolism and nutrition disorders	Polydipsia		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
		Osteoma		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Skin papilloma		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		0	0	0					
		0	0	0					
		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 106 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=19)	
Renal and urinary disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pollakiuria	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Polyuria	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Reproductive system and breast disorders	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Isolated organic (determined by abnormal MRI)			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=19)		(N=9)
Reproductive system and breast disorders	Genital discomfort		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Penile adhesion	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
	Vascular disorders		Moderate	0	0	0			
			Severe	0	0	0			
				0	0	0			
Hypotension			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)			Genotropin n (N=10)			Total (N=28)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR	[95 %-CI] <sup>b</sup>	RR	[95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD	[95 %-CI] <sup>b</sup>					
Any adverse event			14 (77.8%)	9 (90.0%)	23 (82.1%)									
		Mild	10 (55.6%)	3 (30.0%)	13 (46.4%)	3.0943	[0.5785, 16.5521]	1.9024	[0.6727, 5.3800]	0.2681	[-0.0985, 0.6347]			
		Moderate	4 (22.2%)	6 (60.0%)	10 (35.7%)	0.1980	[0.0364, 1.0767]	0.3721	[0.1413, 0.9796]	-0.3913	[-0.7587, -0.0240]			
		Severe	0	0	0									
Infections and infestations			8 (44.4%)	7 (70.0%)	15 (53.6%)									
		Mild	5 (27.8%)	4 (40.0%)	9 (32.1%)	0.6723	[0.1350, 3.3478]	0.7679	[0.2810, 2.0986]	-0.0942	[-0.4782, 0.2898]			
		Moderate	3 (16.7%)	3 (30.0%)	6 (21.4%)	0.4286	[0.0648, 2.8353]	0.5122	[0.1127, 2.3287]	-0.1449	[-0.4778, 0.1880]			
		Severe	0	0	0									
	Respiratory tract infection		4 (22.2%)	2 (20.0%)	6 (21.4%)									
		Mild	3 (16.7%)	1 (10.0%)	4 (14.3%)	2.0000	[0.2417, 16.5484]	1.9333	[0.2754, 13.5707]	0.1014	[-0.1871, 0.3900]			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=18)	n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Respiratory tract infection	Moderate	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.6364 [0.0306, 13.2405]	0.6364 [0.0222, 18.2804]	-0.0290 [-0.2339, 0.1759]
		Severe	0	0	0		0.7902	
		Mild	0	5 (50.0%)	5 (17.9%)	0.0667 [0.0063, 0.7092]	0.1323 [0.0178, 0.9852]	-0.5145 [-0.8230, -0.2060]
	Pharyngitis	Moderate	0	0	0		0.0012	
		Severe	0	0	0			
		Mild	1 (5.6%)	2 (20.0%)	3 (10.7%)	4.2000 [0.1161, 151.9699]	3.0000 [0.1676, 53.7101]	0.0797 [-0.0456, 0.2050]
	Bronchitis	Moderate	0	2 (20.0%)	2 (7.1%)	0.1788 [0.0156, 2.0530]	0.2413 [0.0293, 1.9850]	-0.1884 [-0.4344, 0.0576]
		Severe	0	0	0		0.0837	
		Mild	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.4286 [0.0228, 8.0435]	0.4667 [0.0339, 6.4267]	-0.0580 [-0.2753, 0.1594]
	Enterobiasis	Moderate	0	0	0		0.5716	
		Severe	0	0	0			
		Mild	1 (5.6%)	1 (10.0%)	2 (7.1%)			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Gastroenteritis		0	2 (20.0%)	2 (7.1%)			
		Mild	0	1 (10.0%)	1 (3.6%)	0.2381 [0.0066, 8.6151]	0.3333 [0.0186, 5.9678]	-0.0797 [-0.2506, 0.0912]
		Moderate	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484]	-0.1087 [-0.3025, 0.0851]
	Pneumonia	Severe	0	0	0		0.3173 0.1432	
		Mild	0	0	0		0.1000 0.0339	
		Moderate	0	2 (20.0%)	2 (7.1%)	0.0710 [0.0029, 1.7209]	0.1000 [0.0054, 1.8455]	-0.2174 [-0.4728, 0.0381]
	Respiratory tract infection viral	Severe	0	0	0			
		Mild	1 (5.6%)	1 (10.0%)	2 (7.1%)			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Respiratory tract infection viral	Moderate	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]
		Severe	0	0	0		0.4945	
		Viral infection	2 (11.1%)	0	2 (7.1%)			
		Mild	1 (5.6%)	0	1 (3.6%)	4.2000 [0.1161, 151.9699]	3.0000 [0.1676, 53.7101]	0.0797 [-0.0456, 0.2050]
		Moderate	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]
		Severe	0	0	0		0.4945	
	Laryngitis viral	Mild	0	1 (10.0%)	1 (3.6%)	0.2381 [0.0066, 8.6151]	0.3333 [0.0186, 5.9678]	-0.0797 [-0.2506, 0.0912]
		Moderate	0	0	0		0.3173	
		Severe	0	0	0			
		Mild	0	1 (10.0%)	1 (3.6%)			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Nasopharyngitis		0	1 (10.0%)	1 (3.6%)			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
		Moderate	0	0	0			
	Rhinitis	Severe	0	0	0			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0			
	Rotavirus infection	Severe	0	0	0			
		Mild	1 (5.6%)	0	1 (3.6%)	4.2000 [0.1161, 151.9699]	3.0000 [0.1676, 53.7101] 0.3173	0.0797 [-0.0456, 0.2050]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)			Genotropin n (N=10)			Total (N=28)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR	[95 %-CI] <sup>b</sup>	RR	p-value <sup>c</sup>	RD	[95 %-CI] <sup>b</sup>						
Infections and infestations	Upper respiratory tract infection		0	1 (10.0%)	1 (3.6%)									
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398	0.1667	-0.1087	[0.0050, 3.9017]	[0.0076, 3.6484]	[-0.3025, 0.0851]			
		Moderate	0	0	0									
	Appendicitis	Severe	0	0	0									
		Mild	0	0	0									
		Moderate	0	0	0									
	Atypical pneumonia	Severe	0	0	0									
		Mild	0	0	0									
		Moderate	0	0	0									
	Conjunctivitis	Severe	0	0	0									
		Mild	0	0	0									
		Moderate	0	0	0									
			Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Conjunctivitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Croup infectious	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Cystitis	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Ear infection	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Eczema infected	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 115 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Enteritis infectious		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Gastroenteritis viral	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Helminthic infection	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Hordeolum	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Infected bite	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 116 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Influenza		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Molluscum contagiosum	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Otitis externa	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Otitis media acute	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pharyngitis streptococcal	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 117 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Pharyngotonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pulpitis dental	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Sinusitis	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Tinea pedis	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 118 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=18)	
Infections and infestations	Tooth abscess		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Urinary tract infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Varicella		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Viral upper respiratory tract infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vulvitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 119 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon Genotropin			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			hGH (N=18)	n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Endocrine disorders			6 (33.3%)	3 (30.0%)	9 (32.1%)			
		Mild	6 (33.3%)	3 (30.0%)	9 (32.1%)	0.8889 [0.1442, 5.4794]	0.9333 [0.3245, 2.6841] 0.9013	-0.0217 [-0.3584, 0.3149]
		Moderate	0	0	0			
		Severe	0	0	0			
		Secondary hypothyroidism	5 (27.8%)	0	5 (17.9%)			
		Mild	5 (27.8%)	0	5 (17.9%)	7.8571 [0.3747, 164.7372]	5.5000 [0.3454, 87.5855] 0.0896	0.2536 [0.0447, 0.4625]
		Moderate	0	0	0			
		Severe	0	0	0			
		Diabetes insipidus	1 (5.6%)	1 (10.0%)	2 (7.1%)			
		Mild	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.4286 [0.0228, 8.0435]	0.4667 [0.0339, 6.4267] 0.5716	-0.0580 [-0.2753, 0.1594]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Secondary adrenocortical insufficiency		1 (5.6%)	1 (10.0%)	2 (7.1%)				
		Mild	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.4286 [0.0228, 8.0435]	0.4667 [0.0339, 6.4267] 0.5716	-0.0580 [-0.2753, 0.1594]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Hypothyroidism		0	1 (10.0%)	1 (3.6%)			
			Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
			Moderate	0	0	0			
		Severe	0	0	0				
		Adrenal insufficiency		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 121 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=18)	n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Abdominal pain		3 (16.7%)	2 (20.0%)	5 (17.9%)			
		Mild	3 (16.7%)	2 (20.0%)	5 (17.9%)	0.8077 [0.1222, 5.3397]	0.8333 [0.1817, 3.8225] 0.8197	-0.0362 [-0.3613, 0.2888]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	0	1 (10.0%)	1 (3.6%)			
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0			
Severe	0	0	0					
Mild	1 (5.6%)	0	1 (3.6%)	4.2000 [0.1161, 151.9699]	3.0000 [0.1676, 53.7101] 0.3173	0.0797 [-0.0456, 0.2050]		
Moderate	0	0	0					
Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropi n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Gastrointestinal motility disorder		1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	4.2000 [0.1161, 151.9699]	3.0000 [0.1676, 53.7101] 0.3173	0.0797 [-0.0456, 0.2050]
		Moderate	0	0	0			
		Severe	0	0	0			
	Toothache		0	1 (10.0%)	1 (3.6%)			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
		Moderate	0	0	0			
		Severe	0	0	0			
	Vomiting		1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal discomfort		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Abdominal pain upper		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Aphthous ulcer			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Constipation			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Gastric disorder			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Lip swelling			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=18)	n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Nausea		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Respiratory, thoracic and mediastinal disorders	Cough		3 (16.7%)	2 (20.0%)	5 (17.9%)			
		Mild	2 (11.1%)	1 (10.0%)	3 (10.7%)	0.9231 [0.0694, 12.2803]	0.9333 [0.1007, 8.6496]	-0.0072 [-0.2437, 0.2292]
		Moderate	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.4286 [0.0228, 8.0435]	0.9528 0.4667 [0.0339, 6.4267]	-0.0580 [-0.2753, 0.1594]
		Severe	0	0	0		0.5716	
		Mild	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.4286 [0.0228, 8.0435]	0.4667 [0.0339, 6.4267]	-0.0580 [-0.2753, 0.1594]
		Moderate	0	0	0		0.5716	
		Severe	0	0	0			
		Mild	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.4286 [0.0228, 8.0435]	0.4667 [0.0339, 6.4267]	-0.0580 [-0.2753, 0.1594]
		Moderate	0	0	0		0.5716	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Respiratory disorder		1 (5.6%)	1 (10.0%)	2 (7.1%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
	Epistaxis	Severe	0	0	0			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0			
	Rhinorrhoea	Severe	0	0	0			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
		Moderate	0	1 (10.0%)	1 (3.6%)			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 126 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18) Genotropin n (N=10) Total (N=28)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>			
Respiratory, thoracic and mediastinal disorders	Wheezing		0	1 (10.0%)	1 (3.6%)			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
		Moderate	0	0	0			
	Allergic cough	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Asthma	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Dyspnoea exertional	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Nasal congestion	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Paranasal sinus discomfort	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Rhinitis allergic	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 128 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH (N=18)	n (N=10)			(N=28)	
Respiratory, thoracic and mediastinal disorders	Sinus congestion		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Sleep apnoea syndrome	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
Injury, poisoning and procedural complications			1 (5.6%)	3 (30.0%)	4 (14.3%)			
		Mild	1 (5.6%)	3 (30.0%)	4 (14.3%)	0.0952	0.1556	-0.2754
						[0.0077, 1.1852]	[0.0195, 1.2423]	[-0.5764, 0.0257]
		Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Animal bite	Mild	0	1 (10.0%)	1 (3.6%)	0.1398	0.1667	-0.1087
						[0.0050, 3.9017]	[0.0076, 3.6484]	[-0.3025, 0.0851]
							0.1432	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and degree procedural complications	Burns first		0	1 (10.0%)	1 (3.6%)			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
		Moderate	0	0	0			
	Concussion	Severe	0	0	0			
			0	1 (10.0%)	1 (3.6%)			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
	Upper limb fracture	Moderate	0	0	0			
		Severe	0	0	0			
			1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=18)		(N=10)
Injury, poisoning and fracture procedural complications	Ankle		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Arthropod bite	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Burns second degree	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Contusion	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Face injury	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=18)	(N=10)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Fall		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Head injury	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Laceration	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Ligament sprain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Meniscus injury	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 132 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=18)	(N=10)	(N=28)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Muscle strain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Post-traumatic pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Radius fracture		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thermal burn		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Wrist fracture		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropi n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders			2 (11.1%)	1 (10.0%)	3 (10.7%)				
		Mild	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.7333 [0.0562, 9.5659]	0.7333 [0.0740, 7.2694]	-0.0290 [-0.2730, 0.2150]	
		Moderate	1 (5.6%)	0	1 (3.6%)	4.2000 [0.1161, 151.9699]	0.7902 3.0000 [0.1676, 53.7101]	0.0797 [-0.0456, 0.2050]	
		Severe	0	0	0		0.3173		
		Iron deficiency anaemia		2 (11.1%)	0	2 (7.1%)			
		Mild	1 (5.6%)	0	1 (3.6%)	4.2000 [0.1161, 151.9699]	3.0000 [0.1676, 53.7101]	0.0797 [-0.0456, 0.2050]	
		Moderate	1 (5.6%)	0	1 (3.6%)	4.2000 [0.1161, 151.9699]	3.0000 [0.1676, 53.7101]	0.0797 [-0.0456, 0.2050]	
		Severe	0	0	0		0.3173		
		Anaemia		0	1 (10.0%)	1 (3.6%)			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484]	-0.1087 [-0.3025, 0.0851]	
		Moderate	0	0	0		0.1432		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 134 of 157



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Blood and lymphatic system disorders	Lymphadenopathy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neutropenia	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	0	0	0				
		Mild	0	0	0			
		Moderate	0	0	0			
General disorders and administration site conditions			1 (5.6%)	2 (20.0%)	3 (10.7%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]
		Moderate	0	2 (20.0%)	2 (7.1%)	0.0710 [0.0029, 1.7209]	0.4945 [0.0054, 1.8455]	-0.2174 [-0.4728, 0.0381]
	Face oedema	Severe	0	0	0		0.0339	
		Mild	0	1 (10.0%)	1 (3.6%)			
		Mild	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administrative site conditions	Face oedema	Moderate	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484]	-0.1087 [-0.3025, 0.0851]
		Severe	0	0	0		0.1432	
	Fatigue	Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484]	-0.1087 [-0.3025, 0.0851]
		Moderate	0	0	0		0.1432	
	Influenza like illness	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484]	-0.1087 [-0.3025, 0.0851]
		Severe	0	0	0		0.1432	
	Pyrexia	Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0		0.4945	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 136 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and disturbance administration site conditions	Gait disorders and disturbance administration site conditions		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Injection site atrophy	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Injection site swelling	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Injection site urticaria	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and device administration site conditions	Medical		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Vaccination site pain	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
	Investigations			1 (5.6%)	1 (10.0%)	2 (7.1%)			
		Mild		1 (5.6%)	1 (10.0%)	2 (7.1%)	0.4286 [0.0228, 8.0435]	0.4667 [0.0339, 6.4267]	-0.0580 [-0.2753, 0.1594]
		Moderate		0	0	0		0.5716	
Severe			0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Alanine aminotransferase increased		0	1 (10.0%)	1 (3.6%)				
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Aspartate aminotransferase increased			0	1 (10.0%)	1 (3.6%)			
		Mild	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood cortisol decreased			1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 139 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Cortisol free urine decreased		1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0		0.4945	
	Blood iron decreased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Blood iron increased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Blood thyroid stimulating hormone increased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Eosinophils increased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Insulin-like growth factor increased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroxine decreased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Transaminases increased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 141 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	White blood cell counts decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Skin and subcutaneous tissue disorders	Petechiae		1 (5.6%)	1 (10.0%)	2 (7.1%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]
		Moderate	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.4945 0.1667 [0.0076, 3.6484]	-0.1087 [-0.3025, 0.0851]
		Severe	0	0	0		0.1432	
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0		0.4945	
		Severe	0	0	0			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0		0.4945	
		Severe	0	0	0			
Urticaria			0	1 (10.0%)	1 (3.6%)			
		Mild	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484]	-0.1087 [-0.3025, 0.0851]
		Severe	0	0	0		0.1432	
	Cafe au lait spots	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Severe	0	0	0			
	Dermatitis allergic	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis contact	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eczema	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 143 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=18)	n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Keratosis pilaris		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pityriasis alba	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Rash	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Rash erythematous	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rash pruritic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 144 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Eye disorders	Mild		1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]	
			1 (5.6%)	0	1 (3.6%)				
			0	0	0				
	Moderate		0	0	0				
			0	0	0				
			0	0	0				
	Severe		0	0	0				
			0	0	0				
			0	0	0				
	Hypermetropia	Mild		1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
				1 (5.6%)	0	1 (3.6%)			
				0	0	0			
	Moderate		0	0	0				
			0	0	0				
			0	0	0				
Severe		0	0	0					
		0	0	0					
		0	0	0					
Astigmatism	Mild		0	0	0				
			0	0	0				
			0	0	0				
Moderate		0	0	0					
		0	0	0					
		0	0	0					
Severe		0	0	0					
		0	0	0					
		0	0	0					
Conjunctivitis allergic	Mild		0	0	0				
			0	0	0				
			0	0	0				
Moderate		0	0	0					
		0	0	0					
		0	0	0					
Severe		0	0	0					
		0	0	0					
		0	0	0					
Eye haemorrhage	Mild		0	0	0				
			0	0	0				
			0	0	0				
Moderate		0	0	0					
		0	0	0					
		0	0	0					
Severe		0	0	0					
		0	0	0					
		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18) Genotropin n (N=10) Total (N=28)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Eye disorders	Eye swelling	Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Myopia	Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Strabismus	Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Musculoskeletal and connective tissue disorders			1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]	
		Moderate	0	0	0				
Severe		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 146 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Pain in extremity		1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0			
	Arthralgia	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Arthritis reactive	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Back pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=18)	n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck mass	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pain in jaw	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Synovial cyst	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 148 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders			0	1 (10.0%)	1 (3.6%)			
		Mild	0	0	0			
		Moderate	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
		Severe	0	0	0			
		Headache						
		Mild	0	0	0			
		Moderate	0	1 (10.0%)	1 (3.6%)	0.1398 [0.0050, 3.9017]	0.1667 [0.0076, 3.6484] 0.1432	-0.1087 [-0.3025, 0.0851]
		Severe	0	0	0			
		Dizziness						
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Migraine						
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 149 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders	Post-traumatic headache		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tremor	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Vascular disorders			1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0			
	Hypotension	Severe	0	0	0			
			1 (5.6%)	0	1 (3.6%)			
		Mild	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352] 0.4945	0.0507 [-0.0529, 0.1543]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Cardiac disorders		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinoatrial block		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Sinus tachycardia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tachycardia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Ear and labyrinth disorders		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 151 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=18)	
Ear and labyrinth disorders	Ear pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Hepatobiliary disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Hepatomegaly		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Immune system disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 152 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=28)		[95 %-CI] <sup>b</sup>
			(N=18)	(N=10)		[95 %-CI] <sup>b</sup>			
Immune system disorders	Allergy to animal		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Hypersensitivity	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
	Seasonal allergy	Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				
	Metabolism and nutrition disorders	Polydipsia	Mild	0	0	0			
			Moderate	0	0	0			
			Severe	0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
			Severe	0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 153 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=18)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Osteoma	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Skin papilloma	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Psychiatric disorders	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=18)	Genotropin n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Psychiatric disorders	Affect lability		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Attention deficit/hyperactivity disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Depressive symptom		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Enuresis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 155 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=18)	n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Renal and urinary disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Pollakiuria	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Polyuria	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Reproductive system and breast disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 156 of 157

Table 1.32 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by etiology and extend of GHD Safety Population

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	Severity	TransCon hGH			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			(N=18)	Genotropi n (N=10)	Total (N=28)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Reproductive system and breast disorders	Genital discomfort		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Penile adhesion	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Any adverse event			26 (96.3%)	14 (93.3%)	40 (95.2%)				
		Mild	15 (55.6%)	9 (60.0%)	24 (57.1%)	0.9630 [0.2527, 3.6691]	0.9848 [0.5739, 1.6900]	-0.0091 [-0.3311, 0.3129]	0.1552
		Moderate	11 (40.7%)	5 (33.3%)	16 (38.1%)	1.3846 [0.3521, 5.4447]	1.2273 [0.5120, 2.9420]	0.0758 [-0.2391, 0.3906]	0.3809
		Severe	0	0	0		0.6454		0.9996
Infections and infestations			20 (74.1%)	13 (86.7%)	33 (78.6%)				
		Mild	14 (51.9%)	10 (66.7%)	24 (57.1%)	0.6000 [0.1536, 2.3438]	0.8182 [0.4850, 1.3804]	-0.1212 [-0.4378, 0.1953]	0.3042
		Moderate	6 (22.2%)	3 (20.0%)	9 (21.4%)	1.1765 [0.2350, 5.8907]	1.1364 [0.3185, 4.0547]	0.0273 [-0.2404, 0.2949]	0.5003
		Severe	0	0	0		0.8453		0.9996
	Nasopharyngitis		6 (22.2%)	5 (33.3%)	11 (26.2%)				
	Mild	5 (18.5%)	5 (33.3%)	10 (23.8%)	0.5882 [0.1359, 2.5460]	0.6818 [0.2382, 1.9515]	-0.1061 [-0.4020, 0.1899]	0.6983	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Nasopharyngitis	Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9983
		Severe	0	0	0		0.4090		
	Upper respiratory tract infection	Mild	5 (18.5%)	3 (20.0%)	8 (19.0%)	2.2105 [0.2074, 23.5553]	2.0455 [0.2345, 17.8418]	0.0697 [-0.1213, 0.2607]	0.9991
		Moderate	5 (18.5%)	1 (6.7%)	6 (14.3%)	2.2105 [0.2074, 23.5553]	2.0455 [0.2345, 17.8418]	0.0697 [-0.1213, 0.2607]	0.9991
		Severe	0	2 (13.3%)	2 (4.8%)	0.1200 [0.0053, 2.6917]	0.1391 [0.0071, 2.7080]	-0.1333 [-0.3054, 0.0387]	0.9991
	Pharyngitis streptococcal	Mild	3 (11.1%)	4 (26.7%)	7 (16.7%)	0.6500 [0.0812, 5.2062]	0.6818 [0.1075, 4.3225]	-0.0424 [-0.2522, 0.1674]	1.0000
		Moderate	2 (7.4%)	2 (13.3%)	4 (9.5%)	0.6500 [0.0812, 5.2062]	0.6818 [0.1075, 4.3225]	-0.0424 [-0.2522, 0.1674]	1.0000
		Moderate	1 (3.7%)	2 (13.3%)	3 (7.1%)	0.3095 [0.0255, 3.7637]	0.3409 [0.0339, 3.4310]	-0.0879 [-0.2807, 0.1049]	1.0000
		Severe	0	0	0		0.3429		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pharyngitis		3 (11.1%)	3 (20.0%)	6 (14.3%)				
		Mild	3 (11.1%)	3 (20.0%)	6 (14.3%)	0.6316 [0.1091, 3.6561]	0.6818 [0.1584, 2.9345] 0.6110	-0.0636 [-0.3117, 0.1844]	0.4289
		Moderate	0	0	0				0.9996
	Ear infection	Severe	0	0	0				
		Mild	4 (14.8%)	1 (6.7%)	5 (11.9%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.9972
		Moderate	4 (14.8%)	0	4 (9.5%)	5.5641 [0.2669, 116.0076]	4.8696 [0.2696, 87.9424] 0.1411	0.1364 [-0.0070, 0.2798]	0.9994
	Gastroenteritis	Severe	0	0	0				
		Mild	3 (11.1%)	1 (6.7%)	4 (9.5%)	2.2105 [0.2074, 23.5553]	2.0455 [0.2345, 17.8418] 0.5085	0.0697 [-0.1213, 0.2607]	0.9977
		Moderate	0	0	0				0.9992
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Gastroenteritis viral		3 (11.1%)	0	3 (7.1%)				
		Mild	3 (11.1%)	0	3 (7.1%)	3.7805 [0.1691, 84.5259]	3.4783 [0.1787, 67.7009] 0.2363	0.0909 [-0.0292, 0.2110]	0.9990
		Moderate	0	0	0				
	Sinusitis	Severe	0	0	0				
		Mild	1 (3.7%)	2 (13.3%)	3 (7.1%)	0.1200 [0.0053, 2.6917]	0.1391 [0.0071, 2.7080] 0.0824	-0.1333 [-0.3054, 0.0387]	0.9983
		Moderate	0	2 (13.3%)	2 (4.8%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9998
	Influenza	Severe	1 (3.7%)	0	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9989
		Moderate	0	1 (6.7%)	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 4 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Infections and infestations	Rhinitis		2 (7.4%)	0	2 (4.8%)				
		Mild	2 (7.4%)	0	2 (4.8%)	3.7805 [0.1691, 84.5259]	3.4783 [0.1787, 67.7009] 0.2363	0.0909 [-0.0292, 0.2110]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Viral infection		2 (7.4%)	0	2 (4.8%)				
		Mild	2 (7.4%)	0	2 (4.8%)	3.7805 [0.1691, 84.5259]	3.4783 [0.1787, 67.7009] 0.2363	0.0909 [-0.0292, 0.2110]	0.9996
		Moderate	0	0	0				0.9996
		Severe	0	0	0				
	Atypical pneumonia		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 5 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Conjunctivitis		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				0.9996
		Moderate	1 (3.7%)	0	1 (2.4%)			0.0000 [0.0000, 0.0000]	0.9993
		Severe	0	0	0				
	Conjunctivitis bacterial		0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.9989
		Moderate	0	0	0		0.2259		
		Severe	0	0	0				
	Croup infectious		0	1 (6.7%)	1 (2.4%)				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Hordeolum		0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.9989
Moderate		0	0	0		0.2259			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Molluscum contagiosum		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis externa		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0				
	Pharyngotonsillitis		0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9989
		Moderate	0	0	0				0.9996
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pneumonia		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				
		Moderate	1 (3.7%)	0	1 (2.4%)			0.0000 [0.0000, 0.0000]	0.9974
	Tinea pedis	Severe	0	0	0				
		Mild	1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
	Viral upper respiratory tract infection	Moderate	0	0	0				
		Severe	0	0	0				
			0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9988
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 8 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Vulvitis		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)			0.0000 [0.0000, 0.0000]	0.9993
		Moderate	0	0	0				
	Appendicitis	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
	Bronchitis	Moderate	0	0	0				0.9996
		Severe	0	0	0				
			0	0	0				
	Cystitis	Mild	0	0	0				0.9992
		Moderate	0	0	0				1.0000
		Severe	0	0	0				
	Eczema infected		0	0	0				
		Mild	0	0	0				0.9996
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 9 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Enteritis infectious		0	0	0				
		Mild	0	0	0				0.9996
		Moderate	0	0	0				0.9993
		Severe	0	0	0				
	Enterobiasis		0	0	0				
		Mild	0	0	0				0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Helminthic infection		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				1.0000
		Severe	0	0	0				
	Infected bite		0	0	0				
		Mild	0	0	0				0.9992
		Moderate	0	0	0				
		Severe	0	0	0				
	Laryngitis viral		0	0	0				
		Mild	0	0	0				0.9992
Moderate		0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Otitis media acute		0	0	0				
		Mild	0	0	0				0.9996
		Moderate	0	0	0				0.9992
	Pulpitis dental	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9992
	Respiratory tract infection	Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				
	Respiratory tract infection viral	Mild	0	0	0				1.0000
		Moderate	0	0	0				1.0000
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 11 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value		
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>
Infections and infestations	Rotavirus infection		0	0	0			
		Mild	0	0	0			0.9996
		Moderate	0	0	0			
	Tonsillitis	Severe	0	0	0			
		Mild	0	0	0			0.9992
		Moderate	0	0	0			0.9992
	Tooth abscess	Severe	0	0	0			
		Mild	0	0	0			0.9996
		Moderate	0	0	0			
	Urinary tract infection	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			0.9992
	Varicella	Severe	0	0	0			
		Mild	0	0	0			0.9996
		Moderate	0	0	0			0.9996
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 12 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders			12 (44.4%)	6 (40.0%)	18 (42.9%)				
		Mild	11 (40.7%)	4 (26.7%)	15 (35.7%)	2.2917 [0.5544, 9.4724]	1.7045 [0.6553, 4.4337]	0.1879 [-0.1177, 0.4934]	0.3914
		Moderate	1 (3.7%)	2 (13.3%)	3 (7.1%)	0.3095 [0.0255, 3.7637]	0.2538 [0.0339, 3.4310]	-0.0879 [-0.2807, 0.1049]	1.0000
		Severe	0	0	0		0.3409 [0.0339, 3.4310]		
							0.3429		
		Vomiting							
		Mild	6 (22.2%)	3 (20.0%)	9 (21.4%)	1.9118 [0.3186, 11.4709]	1.7045 [0.3793, 7.6604]	0.0939 [-0.1515, 0.3394]	0.9992
		Moderate	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.4798 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.9989
		Severe	0	0	0		0.2259		
		Diarrhoea							
		Mild	2 (7.4%)	3 (20.0%)	5 (11.9%)	0.4000 [0.0582, 2.7476]	0.4545 [0.0860, 2.4013]	-0.1091 [-0.3445, 0.1263]	0.9989
		Moderate	0	0	0		0.3472		
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Nausea		3 (11.1%)	2 (13.3%)	5 (11.9%)				
		Mild	2 (7.4%)	1 (6.7%)	3 (7.1%)	1.4000 [0.1154, 16.9828]	1.3636 [0.1355, 13.7241]	0.0242 [-0.1500, 0.1985]	0.9993
		Moderate	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.6667 [0.0384, 11.5611]	0.7936 [0.0461, 10.0744]	-0.0212 [-0.1745, 0.1321]	1.0000
	Abdominal pain upper	Severe	0	0	0				
		Mild	3 (11.1%)	1 (6.7%)	4 (9.5%)				
		Moderate	0	0	0				
	Constipation	Severe	0	0	0				
		Mild	2 (7.4%)	0	2 (4.8%)	2.2105 [0.2074, 23.5553]	2.0455 [0.2345, 17.8418]	0.0697 [-0.1213, 0.2607]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9994
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Abdominal pain		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				0.9984
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0		0.4090		
	Aphthous ulcer		0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.9989
		Moderate	0	0	0		0.2259		
		Severe	0	0	0				
	Gastric disorder		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	0	0	0		0.4090		
		Severe	0	0	0				
Abdominal discomfort		0	0	0					
	Mild	0	0	0				0.9993	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 15 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	TransCon hGH (N=27)			Genotropin n (N=15)			Total (N=42)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction n p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>							
Gastrointestinal disorders	Dyspepsia		0	0	0								
		Mild	0	0	0						0.9992		
		Moderate	0	0	0								
	Gastrointestinal motility disorder	Severe	0	0	0								
		Mild	0	0	0						0.9996		
		Moderate	0	0	0								
	Lip swelling	Severe	0	0	0								
		Mild	0	0	0						0.9992		
		Moderate	0	0	0								
	Toothache	Severe	0	0	0								
		Mild	0	0	0						1.0000		
		Moderate	0	0	0								
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 16 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders			13 (48.1%)	5 (33.3%)	18 (42.9%)				
		Mild	9 (33.3%)	4 (26.7%)	13 (31.0%)	1.2833 [0.2998, 5.4936]	1.1932 [0.4224, 3.3706] 0.7399	0.0515 [-0.2451, 0.3481]	0.6617
		Moderate	4 (14.8%)	1 (6.7%)	5 (11.9%)	2.2105 [0.2074, 23.5553]	2.0455 [0.2345, 17.8418] 0.5085	0.0697 [-0.1213, 0.2607]	0.9496
		Severe	0	0	0				
		Cough	3 (11.1%)	3 (20.0%)	6 (14.3%)				
		Mild	3 (11.1%)	2 (13.3%)	5 (11.9%)	0.6500 [0.0812, 5.2062]	0.6818 [0.1075, 4.3225] 0.6873	-0.0424 [-0.2522, 0.1674]	0.8456
		Moderate	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9972
		Severe	0	0	0				
		Asthma	2 (7.4%)	1 (6.7%)	3 (7.1%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 17 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Asthma	Moderate	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	1.0000
		Severe	0	0	0		0.2259		
	Nasal congestion	Mild	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744]	-0.0212 [-0.1745, 0.1321]	1.0000
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
	Sinus congestion	Severe	0	0	0		0.4090		
		Mild	2 (7.4%)	0	2 (4.8%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0		0.4090		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 18 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	TransCon hGH (N=27)		Genotropin n (N=15)		Total (N=42)		Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>							
Respiratory, thoracic and mediastinal disorders	Allergic cough		1 (3.7%)	0	1 (2.4%)							
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.4090	0.9993		
		Moderate	0	0	0							
	Dyspnoea exertional	Severe	0	0	0							
			1 (3.7%)	0	1 (2.4%)							
		Mild	0	0	0							
	Epistaxis	Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.4090	0.9993		
		Severe	0	0	0							
			0	1 (6.7%)	1 (2.4%)							
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.2259	0.9967		
		Moderate	0	0	0							
		Severe	0	0	0					0.9996		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 19 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
	Respiratory disorder	Severe	0	0	0				
		Mild	0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9971
	Rhinitis allergic	Moderate	0	0	0				1.0000
		Severe	0	0	0				
		Mild	1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9992
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		0	1 (6.7%)	1 (2.4%)					
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9993	
		Moderate	0	0	0					
		Severe	0	0	0					
		Sleep apnoea syndrome		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0					
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993	
		Severe	0	0	0					
		Wheezing		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				1.0000	
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993	
		Severe	0	0	0					
		Laryngospasm		0	0	0				
		Mild	0	0	0					
	Moderate	0	0	0				0.9996		
	Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=27)			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			Genotropin (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
General disorders and administrative site conditions			11 (40.7%)	6 (40.0%)	17 (40.5%)				
		Mild	7 (25.9%)	6 (40.0%)	13 (31.0%)	0.5625 [0.1393, 2.2708]	0.6818 [0.2712, 1.7140]	-0.1273 [-0.4373, 0.1827]	0.7629
		Moderate	4 (14.8%)	0	4 (9.5%)	7.5405 [0.3759, 151.2554]	6.2609 [0.3617, 108.3688]	0.1818 [0.0206, 0.3430]	0.9977
		Severe	0	0	0		0.4232 0.0845		
	Pyrexia		10 (37.0%)	4 (26.7%)	14 (33.3%)				
		Mild	6 (22.2%)	4 (26.7%)	10 (23.8%)	0.8088 [0.1773, 3.6902]	0.8523 [0.2728, 2.6629]	-0.0394 [-0.3236, 0.2448]	0.9924
		Moderate	4 (14.8%)	0	4 (9.5%)	7.5405 [0.3759, 151.2554]	6.2609 [0.3617, 108.3688]	0.1818 [0.0206, 0.3430]	0.9994
		Severe	0	0	0		0.7868 0.0845		
	Fatigue		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9986
	Moderate	0	0	0		0.4090			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=27)	Genotropin (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
General disorders and administrative site conditions	Injection site swelling	Injection site		0	1 (6.7%)	1 (2.4%)					
			Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9989	
			Moderate	0	0	0					
			Severe	0	0	0					
			Injection site urticaria	Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
				Moderate	0	0	0				
	Medical device discomfort	Medical device	discomfort		0	1 (6.7%)	1 (2.4%)				
				Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9989
				Moderate	0	0	0				
				Severe	0	0	0				
					0	1 (6.7%)	1 (2.4%)				
					0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 23 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=27)	Genotropin (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
General disorders and administrative site conditions	Vaccination site pain		0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9989
		Moderate	0	0	0				
	Face oedema	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9992
	Gait disturbance	Severe	0	0	0				
		Mild	0	0	0				0.9996
		Moderate	0	0	0				
	Influenza like illness	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9992
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 24 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=27)			Genotropin n (N=15)			Total (N=42)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
General disorders and administration site conditions	Injection site atrophy		0	0	0								
		Mild	0	0	0						0.9992		
		Moderate	0	0	0								
		Severe	0	0	0								
Nervous system disorders			10 (37.0%)	7 (46.7%)	17 (40.5%)								
		Mild	6 (22.2%)	5 (33.3%)	11 (26.2%)	0.7500 [0.1802, 3.1207]	0.8182 [0.3044, 2.1994]	-0.0606 [-0.3632, 0.2420]	0.6961	0.9421			
		Moderate	4 (14.8%)	2 (13.3%)	6 (14.3%)	1.4444 [0.2291, 9.1059]	1.3636 [0.2850, 6.5242]	0.0485 [-0.1872, 0.2842]	0.6984	0.9994			
		Severe	0	0	0								
	Headache		9 (33.3%)	5 (33.3%)	14 (33.3%)								
		Mild	5 (18.5%)	3 (20.0%)	8 (19.0%)	1.1765 [0.2350, 5.8907]	1.1364 [0.3185, 4.0547]	0.0273 [-0.2404, 0.2949]	0.8453	0.9994			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=27)			Genotropin n (N=15)			Total (N=42)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>										
Nervous system disorders	Headache	Moderate	4 (14.8%)	2 (13.3%)	6 (14.3%)	1.4444 [0.2291, 9.1059]	1.3636 [0.2850, 6.5242]	0.0485 [-0.1872, 0.2842]	0.9994						
		Severe	0	0	0		0.6984								
	Dizziness	Mild	2 (7.4%)	1 (6.7%)	3 (7.1%)	1.4000 [0.1154, 16.9828]	1.3636 [0.1355, 13.7241]	0.0242 [-0.1500, 0.1985]	1.0000						
		Moderate	2 (7.4%)	1 (6.7%)	3 (7.1%)		0.7936								
	Post-traumatic headache	Severe	0	0	0										
		Mild	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744]	-0.0212 [-0.1745, 0.1321]	1.0000						
	Migraine	Moderate	0	0	0										
		Severe	0	0	0										
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.9989						
		Moderate	0	1 (6.7%)	1 (2.4%)		0.2259								
		Severe	0	0	0										

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Nervous system disorders	Tremor		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
Musculoskeletal and connective tissue disorders		Severe	0	0	0				
			8 (29.6%)	4 (26.7%)	12 (28.6%)				
		Mild	6 (22.2%)	4 (26.7%)	10 (23.8%)	0.8088 [0.1773, 3.6902]	0.8523 [0.2728, 2.6629]	-0.0394 [-0.3236, 0.2448]	0.9924
	Arthralgia	Moderate	2 (7.4%)	0	2 (4.8%)	3.7805 [0.1691, 84.5259]	3.4783 [0.1787, 67.7009] 0.2363	0.0909 [-0.0292, 0.2110]	0.9993
		Severe	0	0	0				
		Mild	5 (18.5%)	1 (6.7%)	6 (14.3%)	3.1111 [0.3119, 31.0283]	2.7273 [0.3371, 22.0657] 0.3211	0.1152 [-0.0896, 0.3199]	1.0000
		Moderate	0	0	0				
Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Class	Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
				TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Pain in extremity		3 (11.1%)	3 (20.0%)	6 (14.3%)					
		Mild	2 (7.4%)	3 (20.0%)	5 (11.9%)	0.4000 [0.0582, 2.7476]	0.4545 [0.0860, 2.4013]	-0.1091 [-0.3445, 0.1263]	0.9991	
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993	
	Musculoskeletal pain	Severe	0	0	0		0.4090			
		Mild	2 (7.4%)	0	2 (4.8%)					
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993	
	Neck pain	Severe	0	0	0		0.4090			
		Mild	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744]	-0.0212 [-0.1745, 0.1321]	1.0000	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Back pain		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
	Neck mass	Severe	0	0	0				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	0	0	0				
	Pain in jaw	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 29 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)				
Musculoskeletal and connective tissue disorders	Arthritis reactive		0	0	0				
		Mild	0	0	0				0.9996
		Moderate	0	0	0				
	Synovial cyst	Severe	0	0	0				
		Mild	0	0	0				0.9992
		Moderate	0	0	0				
	Injury, poisoning and procedural complications	Severe	0	0	0				
			7 (25.9%)	2 (13.3%)	9 (21.4%)				
		Mild	4 (14.8%)	2 (13.3%)	6 (14.3%)	1.4444 [0.2291, 9.1059]	1.3636 [0.2850, 6.5242] 0.6984	0.0485 [-0.1872, 0.2842]	0.5925
Moderate		3 (11.1%)	0	3 (7.1%)	5.5641 [0.2669, 116.0076]	4.8696 [0.2696, 87.9424] 0.1411	0.1364 [-0.0070, 0.2798]	0.9993	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 30 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Post-traumatic pain		1 (3.7%)	1 (6.7%)	2 (4.8%)				
		Mild	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744] 0.7823	-0.0212 [-0.1745, 0.1321]	1.0000
		Moderate	0	0	0				
	Animal bite	Severe	0	0	0				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9983
		Moderate	0	0	0				
	Ankle fracture	Severe	0	0	0				
		Mild	1 (3.7%)	0	1 (2.4%)				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 31 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and bite procedural complications	Arthropod			0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9988	
		Moderate	0	0	0					
		Severe	0	0	0					
		Face injury	Mild	1 (3.7%)	0	1 (2.4%)				
			Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Head injury	Severe	0	0	0				
			Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 32 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=27)		Genotropin n (N=15)		Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value				
Injury, poisoning and procedural complications	Ligament sprain		1 (3.7%)	0	1 (2.4%)					
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993	
		Moderate	0	0	0					
	Muscle strain	Severe	0	0	0					
			1 (3.7%)	0	1 (2.4%)					
		Mild	0	0	0					
	Thermal burn	Moderate		1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
			Severe	0	0	0				
		Mild		0	1 (6.7%)	1 (2.4%)				
				0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9989
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 33 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Class	Organ Class	Preferred Term	Severity	Incidence		Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
				TransCon hGH (N=27)	Genotropin n (N=15)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Injury, poisoning and procedural complications	Wrist fracture			1 (3.7%)	0	1 (2.4%)					
			Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993	
			Moderate	0	0	0					
	Burns first degree			Severe	0	0	0				
				Mild	0	0	0				0.9992
				Moderate	0	0	0				
	Burns second degree			Severe	0	0	0				
				Mild	0	0	0				0.9996
				Moderate	0	0	0				
	Concussion			Severe	0	0	0				
				Mild	0	0	0				0.9992
				Moderate	0	0	0				
				Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 34 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	TransCon hGH (N=27)			Genotropin n (N=15)			Total (N=42)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Injury, poisoning and procedural complications	Contusion		0	0	0								
		Mild	0	0	0					0.9992			
		Moderate	0	0	0					0.9996			
	Fall		0	0	0								
		Mild	0	0	0					0.9992			
		Moderate	0	0	0								
	Laceration		0	0	0								
		Mild	0	0	0					0.9992			
		Moderate	0	0	0								
	Meniscus injury		0	0	0								
		Mild	0	0	0					0.9992			
		Moderate	0	0	0								
	Radius fracture		0	0	0								
		Mild	0	0	0					0.9996			
		Moderate	0	0	0								
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 35 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	TransCon hGH (N=27)			Genotropin n (N=15)			Total (N=42)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Injury, poisoning and procedural complications	Upper limb fracture		0	0	0								
		Mild	0	0	0							0.9996	
		Moderate	0	0	0								
		Severe	0	0	0								
Skin and subcutaneous tissue disorders	Rash		7 (25.9%)	1 (6.7%)	8 (19.0%)								
		Mild	6 (22.2%)	1 (6.7%)	7 (16.7%)	3.1111 [0.3119, 31.0283]	2.7273 [0.3371, 22.0657]	0.1152 [-0.0896, 0.3199]	0.3211	0.4968			
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.4090	0.9987			
		Severe	0	0	0								
		Mild	3 (11.1%)	1 (6.7%)	4 (9.5%)	1.4000 [0.1154, 16.9828]	1.3636 [0.1355, 13.7241]	0.0242 [-0.1500, 0.1985]	0.7936	1.0000			
		Moderate	0	0	0								
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 36 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Cafe au lait spots		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)			0.0000 [0.0000, 0.0000]	0.9993
		Moderate	0	0	0				
	Eczema	Severe	0	0	0				
		Mild	1 (3.7%)	0	1 (2.4%)				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
	Keratosis pilaris	Severe	0	0	0		0.4090		
		Mild	1 (3.7%)	0	1 (2.4%)				
		Moderate	0	0	0			0.0000 [0.0000, 0.0000]	0.9993
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Pityriasis alba		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)			0.0000 [0.0000, 0.0000]	0.9993
		Moderate Severe	0 0	0 0	0 0				
	Rash erythematous		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate Severe	0 0	0 0	0 0				
	Urticaria		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate Severe	0 0	0 0	0 0				0.9992

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 38 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	TransCon hGH (N=27)			Genotropin n (N=15)			Total (N=42)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>							
Skin and subcutaneous tissue disorders	Dermatitis allergic		0	0	0							0.9992	
		Mild	0	0	0								
		Moderate	0	0	0								
	Dermatitis contact	Severe	0	0	0							0.9992	
		Mild	0	0	0								
		Moderate	0	0	0								
	Petechiae	Severe	0	0	0							0.9996	
		Mild	0	0	0								
		Moderate	0	0	0								
	Rash pruritic	Severe	0	0	0							0.9992	
		Mild	0	0	0								
		Moderate	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 39 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Immune system disorders				5 (18.5%)	2 (13.3%)	7 (16.7%)				
			Mild	4 (14.8%)	2 (13.3%)	6 (14.3%)	1.4444 [0.2291, 9.1059]	1.3636 [0.2850, 6.5242]	0.0485 [-0.1872, 0.2842]	0.9986
			Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
			Severe	0	0	0		0.6984 0.4090		
		Seasonal allergy		3 (11.1%)	1 (6.7%)	4 (9.5%)				
			Mild	3 (11.1%)	1 (6.7%)	4 (9.5%)	2.2105 [0.2074, 23.5553]	2.0455 [0.2345, 17.8418]	0.0697 [-0.1213, 0.2607]	0.9992
			Moderate	0	0	0		0.5085		
			Severe	0	0	0				
		Hypersensitivity		1 (3.7%)	1 (6.7%)	2 (4.8%)				
			Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.9989
			Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
			Severe	0	0	0		0.4090		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Immune system disorders	Allergy to animal		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9998
		Moderate	0	0	0		0.4090		
		Severe	0	0	0				
Psychiatric disorders	Attention deficit/hyperactivity disorder		3 (11.1%)	1 (6.7%)	4 (9.5%)				
		Mild	2 (7.4%)	1 (6.7%)	3 (7.1%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744]	-0.0212 [-0.1745, 0.1321]	0.9993
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0		0.4090		
		Mild	1 (3.7%)	1 (6.7%)	2 (4.8%)				
		Mild	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	1.0000
	Moderate	0	0	0		0.2259			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>							
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value	
Psychiatric disorders	Affect lability		1 (3.7%)	0	1 (2.4%)					
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993	
		Moderate	0	0	0					
	Depressive symptom	Severe	0	0	0					
			1 (3.7%)	0	1 (2.4%)					
		Mild	0	0	0					
	Enuresis	Moderate		1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
			Severe	0	0	0				
			Mild	0	0	0				
		Severe		0	0	0				
			Mild	0	0	0				0.9992
			Moderate	0	0	0				
	Severe	0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 42 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders				2 (7.4%)	1 (6.7%)	3 (7.1%)				
			Mild	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744]	-0.0212 [-0.1745, 0.1321]	0.8724
			Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9998
			Severe	0	0	0		0.7823 0.4090		
			Lymphadenopathy	1 (3.7%)	1 (6.7%)	2 (4.8%)				
			Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380]	-0.0667 [-0.1929, 0.0596]	0.9989
			Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
			Severe	0	0	0		0.2259 0.4090		
			Neutropenia	1 (3.7%)	0	1 (2.4%)				
			Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9998
			Moderate	0	0	0		0.4090		
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 43 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	TransCon hGH (N=27)			Genotropin n (N=15)			Total (N=42)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Blood and lymphatic system disorders	Anaemia		0	0	0								
		Mild	0	0	0						0.9980		
		Moderate	0	0	0								
	Iron deficiency anaemia		0	0	0								
		Mild	0	0	0						0.9992		
		Moderate	0	0	0						0.9996		
	Eye disorders			3 (11.1%)	0	3 (7.1%)							
			Mild	3 (11.1%)	0	3 (7.1%)	3.7805 [0.1691, 84.5259]	3.4783 [0.1787, 67.7009]	0.0909 [-0.0292, 0.2110]			0.9992	
			Moderate	0	0	0		0.2363					
Conjunctivitis allergic			1 (3.7%)	0	1 (2.4%)								
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]			0.9993		
		Moderate	0	0	0		0.4090						
			0	0	0								
			0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Eye disorders	Eye haemorrhage		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye swelling		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)			0.0000 [0.0000, 0.0000]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Astigmatism		0	0	0				
		Mild	0	0	0				0.9992
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypermetropia		0	0	0				
		Mild	0	0	0				0.9992
		Moderate	0	0	0				
	Severe	0	0	0					
Myopia		0	0	0					
	Mild	0	0	0				0.9992	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 45 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=27)	Genotropi n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
Eye disorders	Strabismus		0	0	0				
		Mild	0	0	0				1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
Investigations			3 (11.1%)	0	3 (7.1%)				
		Mild	3 (11.1%)	0	3 (7.1%)	3.7805 [0.1691, 84.5259]	3.4783 [0.1787, 67.7009] 0.2363	0.0909 [-0.0292, 0.2110]	0.5035
		Moderate	0	0	0				
		Severe	0	0	0				
		Blood thyroid stimulating hormone increased	1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 46 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Insulin-like growth factor increased		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)			0.0000 [0.0000, 0.0000]	0.9998
		Moderate	0	0	0				
	White blood cell count decreased	Severe	0	0	0				
			1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418]	0.0455 [-0.0416, 0.1325]	0.9993
	Alanine aminotransferase increased	Moderate	0	0	0		0.4090		
		Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9992
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 47 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	
Investigations	Aspartate aminotransferase increased		0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	
	Blood cortisol decreased	Severe	0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	
	Blood iron decreased	Severe	0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	
	Blood iron increased	Severe	0	0	0	
		Mild	0	0	0	
		Moderate	0	0	0	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 48 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value			
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Cortisol free urine decreased		0	0	0				
		Mild	0	0	0				0.9996
		Moderate	0	0	0				
	Eosinophil count increased	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9993
	Thyroxine decreased	Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				
	Transaminases increased	Mild	0	0	0				0.9992
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 49 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Class	Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
				TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				2 (7.4%)	1 (6.7%)	3 (7.1%)					
			Mild	2 (7.4%)	1 (6.7%)	3 (7.1%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744] 0.7823	-0.0212 [-0.1745, 0.1321]	0.9985	
			Moderate	0	0	0					
			Severe	0	0	0					
			Skin papilloma		1 (3.7%)	1 (6.7%)	2 (4.8%)				
				Mild	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744] 0.7823	-0.0212 [-0.1745, 0.1321]	0.9986
				Moderate	0	0	0				
				Severe	0	0	0				
			Osteoma		1 (3.7%)	0	1 (2.4%)				
				Mild	1 (3.7%)	0	1 (2.4%)			0.0000 [0.0000, 0.0000]	0.9993
				Moderate	0	0	0				
					Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 50 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Endocrine disorders			0	2 (13.3%)	2 (4.8%)				
		Mild	0	2 (13.3%)	2 (4.8%)	0.1200 [0.0053, 2.6917]	0.1391 [0.0071, 2.7080] 0.0824	-0.1333 [-0.3054, 0.0387]	0.9964
		Moderate	0	0	0				0.9996
		Severe	0	0	0				
		Secondary hypothyroidism	0	2 (13.3%)	2 (4.8%)				
		Mild	0	2 (13.3%)	2 (4.8%)	0.1200 [0.0053, 2.6917]	0.1391 [0.0071, 2.7080] 0.0824	-0.1333 [-0.3054, 0.0387]	0.9989
		Moderate	0	0	0				0.9996
		Severe	0	0	0				
		Adrenal insufficiency	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9992
		Severe	0	0	0				
		Diabetes insipidus	0	0	0				
		Mild	0	0	0				1.0000
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 51 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value		
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>			
Endocrine disorders	Hypothyroidism		0	0	0				0.9992		
		Mild	0	0	0						
		Moderate	0	0	0						
		Severe	0	0	0						
	Secondary adrenocortical insufficiency		0	0	0				0.9977		
		Mild	0	0	0						
		Moderate	0	0	0						
		Severe	0	0	0						
		Renal and urinary disorders		2 (7.4%)	0	2 (4.8%)					0.9993
			Mild	2 (7.4%)	0	2 (4.8%)	3.7805 [0.1691, 84.5259]	3.4783 [0.1787, 67.7009] 0.2363		0.0909 [-0.0292, 0.2110]	
Moderate	0		0	0							
Severe	0		0	0							
Pollakiuria		1 (3.7%)	0	1 (2.4%)				0.9993			
	Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]				
	Moderate	0	0	0							
	Severe	0	0	0							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Renal and urinary disorders	Polyuria		1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
Cardiac disorders			1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				0.9996
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Severe	0	0	0				
	Sinus tachycardia		1 (3.7%)	0	1 (2.4%)				
		Mild	0	0	0				
		Moderate	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 53 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Cardiac disorders	Sinoatrial block		0	0	0				0.9996
		Mild	0	0	0				
		Moderate	0	0	0				
	Tachycardia	Severe	0	0	0				0.9996
			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
Ear and labyrinth disorders			1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)		0.0000 [0.0000, 0.0000]	1.0000	
		Moderate	0	0	0				
	Ear pain	Severe	0	0	0				
			1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)		0.0000 [0.0000, 0.0000]	1.0000	
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 54 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Metabolism and nutrition disorders			1 (3.7%)	0	1 (2.4%)				
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
		Polydipsia							
		Mild	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
Reproductive system and breast disorders			0	1 (6.7%)	1 (2.4%)				
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 55 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>							
			TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value	
Reproductive system and breast disorders	Penile adhesion		0	1 (6.7%)	1 (2.4%)					
		Mild	0	1 (6.7%)	1 (2.4%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	0.9998	
		Moderate	0	0	0					
	Genital discomfort	Severe	0	0	0					
			0	0	0					
		Mild	0	0	0				0.9992	
		Moderate	0	0	0					
	Hepatobiliary disorders	Hepatomegaly	Severe	0	0	0				
			Mild	0	0	0				0.9992
			Moderate	0	0	0				
		Mild	0	0	0				0.9992	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 56 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

North America

System Class	Organ Class	Preferred Term	Severity	TransCon hGH (N=27)	Genotropin n (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
							OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Vascular disorders				0	0	0				
			Mild	0	0	0				0.9992
			Moderate	0	0	0				
			Severe	0	0	0				
		Hypotension		0	0	0				
			Mild	0	0	0				0.9992
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 57 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH (N=66)	n (N=31)			(N=97)	
Any adverse event			44 (66.7%)	19 (61.3%)	63 (64.9%)			
		Mild	28 (42.4%)	7 (22.6%)	35 (36.1%)	2.6284 [0.9748, 7.0870]	1.9448 [0.9292, 4.0702] 0.0542	0.2054 [0.0159, 0.3950]
		Moderate	15 (22.7%)	12 (38.7%)	27 (27.8%)	0.5049 [0.1990, 1.2809]	0.6266 [0.3387, 1.1595] 0.1470	-0.1437 [-0.3449, 0.0575]
		Severe	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
			30 (45.5%)	16 (51.6%)	46 (47.4%)			
		Mild	19 (28.8%)	6 (19.4%)	25 (25.8%)	1.8734 [0.6485, 5.4115]	1.5941 [0.7086, 3.5861] 0.2463	0.1124 [-0.0639, 0.2887]
		Moderate	10 (15.2%)	10 (32.3%)	20 (20.6%)	0.3935 [0.1416, 1.0941]	0.4893 [0.2239, 1.0695] 0.0735	-0.1610 [-0.3476, 0.0256]
		Severe	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
	Infections and infestations			30 (45.5%)	16 (51.6%)	46 (47.4%)		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 58 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Pharyngitis		5 (7.6%)	6 (19.4%)	11 (11.3%)			
		Mild	4 (6.1%)	6 (19.4%)	10 (10.3%)	0.3010 [0.0772, 1.1737]	0.3536 [0.1102, 1.1352]	-0.1223 [-0.2732, 0.0286]
		Moderate	1 (1.5%)	0	1 (1.0%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717]	0.0200 [-0.0143, 0.0542]
	Respiratory tract infection	Severe	0	0	0		0.4008	
		Mild	5 (7.6%)	2 (6.5%)	7 (7.2%)	1.3495 [0.2824, 6.4489]	1.3424 [0.3121, 5.7742]	0.0238 [-0.0950, 0.1426]
		Moderate	2 (3.0%)	1 (3.2%)	3 (3.1%)	0.9533 [0.0721, 12.5981]	0.9533 [0.0609, 14.9229]	-0.0013 [-0.0732, 0.0705]
		Severe	0	0	0		0.9727	
	Bronchitis	Mild	2 (3.0%)	0	2 (2.1%)	1.6492 [0.1641, 16.5757]	1.6183 [0.1758, 14.8944]	0.0334 [-0.0106, 0.0775]

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 59 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Bronchitis	Moderate	1 (1.5%)	3 (9.7%)	4 (4.1%)	0.1890 [0.0188, 1.9013]	0.2186 [0.0280, 1.7044]	-0.0714 [-0.1779, 0.0352]
		Severe	0	0	0		0.1142	
	Respiratory tract infection viral	Mild	2 (3.0%)	2 (6.5%)	4 (4.1%)	0.4145 [0.0516, 3.3283]	0.4276 [0.0538, 3.4001]	-0.0361 [-0.1311, 0.0589]
		Moderate	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]
	Nasopharyngitis	Severe	0	0	0		0.5335	
		Mild	3 (4.5%)	0	3 (3.1%)	6.0345 [0.2834, 128.4722]	5.0556 [0.2849, 89.7045]	0.0599 [0.0022, 0.1176]
		Moderate	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524]	-0.0283 [-0.0870, 0.0305]
		Severe	0	0	0		0.2340	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 60 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Rhinitis		2 (3.0%)	2 (6.5%)	4 (4.1%)			
		Mild	2 (3.0%)	2 (6.5%)	4 (4.1%)	0.5657 [0.0687, 4.6573]	0.5913 [0.0787, 4.4405] 0.6089	-0.0231 [-0.1147, 0.0684]
		Moderate	0	0	0			
	Viral infection	Severe	0	0	0			
			4 (6.1%)	0	4 (4.1%)			
		Mild	3 (4.5%)	0	3 (3.1%)	2.2548 [0.2374, 21.4135]	2.1607 [0.2501, 18.6684] 0.1760	0.0534 [-0.0015, 0.1083]
	Enteritis infectious	Moderate	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Severe	0	0	0			
		Mild	1 (1.5%)	2 (6.5%)	3 (3.1%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	2 (6.5%)	2 (2.1%)	0.1646 [0.0164, 1.6564]	0.1798 [0.0195, 1.6549] 0.0498	-0.0631 [-0.1491, 0.0230]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 61 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Enterobiasis		1 (1.5%)	1 (3.2%)	2 (2.1%)			
		Mild	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.3750 [0.0223, 6.3181]	0.3878 [0.0255, 5.8905] 0.4836	-0.0213 [-0.0916, 0.0490]
		Moderate	0	0	0			
	Gastroenteritis	Severe	0	0	0			
			0	2 (6.5%)	2 (2.1%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524]	-0.0283 [-0.0870, 0.0305]
	Helminthic infection	Moderate	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375]	-0.0348 [-0.0995, 0.0299]
		Severe	0	0	0			
			1 (1.5%)	1 (3.2%)	2 (2.1%)			
		Mild	0	0	0			
		Moderate	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.3750 [0.0223, 6.3181]	0.3878 [0.0255, 5.8905] 0.4836	-0.0213 [-0.0916, 0.0490]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 62 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropi n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Otitis media acute		1 (1.5%)	1 (3.2%)	2 (2.1%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]
	Pneumonia	Severe	0	0	0			
		Mild	0	2 (6.5%)	2 (2.1%)			
		Moderate	0	2 (6.5%)	2 (2.1%)	0.0707 [0.0032, 1.5460]	0.0800 [0.0040, 1.5936] 0.0221	-0.0695 [-0.1593, 0.0202]
	Varicella	Severe	0	0	0			
		Mild	2 (3.0%)	0	2 (2.1%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 63 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropi n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>
							[95 %-CI] <sup>b</sup>	
Infections and infestations	Appendicitis		1 (1.5%)	0	1 (1.0%)			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]
							0.5335	
	Conjunctivitis		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			
							0.5335	
	Cystitis		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			
						0.5335		
Ear infection		1 (1.5%)	0	1 (1.0%)				
	Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]	
	Moderate	0	0	0				
	Severe	0	0	0				
						0.5335		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 64 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Laryngitis viral		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524] 0.2340	-0.0283 [-0.0870, 0.0305]
		Moderate	0	0	0			
	Pharyngotonsillitis	Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
		Mild	0	0	0			
	Rotavirus infection	Moderate	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
	Sinusitis	Mild	1 (1.5%)	0	1 (1.0%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717] 0.4008	0.0200 [-0.0143, 0.0542]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 65 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH (N=66)	n (N=31)			(N=97)	
Infections and infestations	Sinusitis	Moderate	1 (1.5%)	0	1 (1.0%)	2.2727	2.1667	0.0200
						[0.0852, 60.6357]	[0.0957, 49.0717]	[-0.0143, 0.0542]
		Severe	0	0	0		0.4008	
	Tonsillitis		0	1 (3.2%)	1 (1.0%)			
		Mild	0	0	0			
		Moderate	0	1 (3.2%)	1 (1.0%)	0.2190	0.2407	-0.0283
						[0.0082, 5.8561]	[0.0106, 5.4524]	[-0.0870, 0.0305]
		Severe	0	0	0		0.2340	
	Tooth abscess		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062	1.2000	0.0135
						[0.0471, 30.9054]	[0.0510, 28.2372]	[-0.0149, 0.0418]
						0.5335		
		Moderate	0	0	0			
		Severe	0	0	0			
Upper respiratory tract infection		1 (1.5%)	0	1 (1.0%)				
	Mild	1 (1.5%)	0	1 (1.0%)	1.2062	1.2000	0.0135	
					[0.0471, 30.9054]	[0.0510, 28.2372]	[-0.0149, 0.0418]	
					0.5335			
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 66 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Urinary tract infection		0	1 (3.2%)	1 (1.0%)			
		Mild	0	0	0			
		Moderate	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524]	-0.0283 [-0.0870, 0.0305]
		Severe	0	0	0		0.2340	
	Atypical pneumonia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Croup infectious		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 67 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=66)	(N=31)	(N=97)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Infections and infestations	Eczema infected		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Gastroenteritis viral	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Hordeolum	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Infected bite	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Influenza	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 68 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=66)	(N=31)	(N=97)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Infections and infestations	Molluscum contagiosum		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis externa		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngitis streptococcal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pulpitis dental		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 69 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Tinea pedis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Viral upper respiratory tract infection	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Vulvitis	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Respiratory, thoracic and mediastinal disorders	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
			11 (16.7%)	2 (6.5%)	13 (13.4%)			
	Mild	8 (12.1%)	1 (3.2%)	9 (9.3%)	4.7078 [0.5069, 43.7252]	4.2716 [0.4685, 38.9499]	0.0925 [-0.0065, 0.1916]	
						0.1521		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 70 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	3 (4.5%)	1 (3.2%)	4 (4.1%)	1.3646 [0.1436, 12.9713]	1.3498 [0.1626, 11.2043]	0.0122 [-0.0711, 0.0954]
		Severe	0	0	0	0.7819		
		Mild	5 (7.6%)	1 (3.2%)	6 (6.2%)	1.7856 [0.1975, 16.1423]	1.7375 [0.2198, 13.7337]	0.0256 [-0.0617, 0.1129]
	Respiratory disorder	Moderate	4 (6.1%)	1 (3.2%)	5 (5.2%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717]	0.0200 [-0.0143, 0.0542]
		Severe	1 (1.5%)	0	1 (1.0%)	0.4008		
		Mild	3 (4.5%)	1 (3.2%)	4 (4.1%)	1.6492 [0.1641, 16.5757]	1.6183 [0.1758, 14.8944]	0.0334 [-0.0106, 0.0775]
		Moderate	2 (3.0%)	0	2 (2.1%)	0.3750 [0.0223, 6.3181]	0.3878 [0.0255, 5.8905]	-0.0213 [-0.0916, 0.0490]
	Severe	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.4836			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 71 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Epistaxis		2 (3.0%)	0	2 (2.1%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
	Rhinitis allergic	Severe	0	0	0			
		Mild	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.4766 [0.0238, 9.5351]	0.4766 [0.0189, 12.0087] 0.6452	-0.0148 [-0.0805, 0.0509]
		Moderate	0	0	0			
	Laryngospasm	Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717] 0.4008	0.0200 [-0.0143, 0.0542]
		Moderate	1 (1.5%)	0	1 (1.0%)			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 72 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Allergic cough		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Asthma	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Dyspnoea exertional	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Nasal congestion	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Paranasal sinus discomfort	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 73 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=66)	(N=31)	(N=97)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Sinus congestion	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Sleep apnoea syndrome	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Wheezing	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 74 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Endocrine disorders	Mild		7 (10.6%)	3 (9.7%)	10 (10.3%)			
			6 (9.1%)	3 (9.7%)	9 (9.3%)	0.8827 [0.2018, 3.8604]	0.8932 [0.2342, 3.4071]	-0.0104 [-0.1362, 0.1153]
							0.8700	
	Moderate		1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]
							0.5335	
	Severe		0	0	0			
			6 (9.1%)	1 (3.2%)	7 (7.2%)			
	Secondary hypothyroidism	Mild	5 (7.6%)	1 (3.2%)	6 (6.2%)	2.7132 [0.2734, 26.9297]	2.6125 [0.2572, 26.5385]	0.0456 [-0.0417, 0.1329]
							0.3954	
Moderate		1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]	
						0.5335		
Severe		0	0	0				
		1 (1.5%)	1 (3.2%)	2 (2.1%)				
Diabetes insipidus	Mild	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.3750 [0.0223, 6.3181]	0.3878 [0.0255, 5.8905]	-0.0213 [-0.0916, 0.0490]	
						0.4836		
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 75 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Hypothyroidism		0	1 (3.2%)	1 (1.0%)				
		Mild	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Secondary adrenocortical insufficiency			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Adrenal insufficiency			0	0	0		
			Mild	0	0	0			
	Moderate		0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 76 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications			4 (6.1%)	4 (12.9%)	8 (8.2%)			
		Mild	2 (3.0%)	3 (9.7%)	5 (5.2%)	0.2270 [0.0347, 1.4828]	0.2585 [0.0468, 1.4278] 0.0994	-0.0773 [-0.1910, 0.0363]
		Moderate	2 (3.0%)	1 (3.2%)	3 (3.1%)	0.9612 [0.0918, 10.0622]	0.9620 [0.1064, 8.7001] 0.9727	-0.0013 [-0.0803, 0.0776]
		Severe	0	0	0			
	Animal bite		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Burns first degree		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 77 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropi n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Burns second degree		1 (1.5%)	0	1 (1.0%)			
		Mild	0	0	0			
		Moderate	1 (1.5%)	0	1 (1.0%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717] 0.4008	0.0200 [-0.0143, 0.0542]
	Concussion	Severe	0	0	0			
		Mild	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]
		Moderate	0	0	0			
	Contusion	Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)			
		Moderate	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
	Meniscus injury	Severe	0	0	0			
Mild		0	1 (3.2%)	1 (1.0%)				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 78 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and injury procedural complications	Meniscus	Moderate	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375]	-0.0348 [-0.0995, 0.0299]
		Severe	0	0	0		0.1083	
		Radius fracture	1 (1.5%)	0	1 (1.0%)			
	Upper limb fracture	Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0		0.5335	
		Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0		0.5335	
		Severe	0	0	0			
	Ankle fracture	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 79 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=66)	(N=31)	(N=97)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Injury, poisoning and bite procedural complications	Arthropod		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Face injury	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Fall	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Head injury	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Laceration	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 80 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=66)	(N=31)	(N=97)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Ligament sprain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Muscle strain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Post-traumatic pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Thermal burn	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Wrist fracture	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 81 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropi n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders			5 (7.6%)	1 (3.2%)	6 (6.2%)			
		Mild	5 (7.6%)	1 (3.2%)	6 (6.2%)	2.3973 [0.2867, 20.0439]	2.3118 [0.3137, 17.0335] 0.3954	0.0456 [-0.0481, 0.1393]
		Moderate	0	0	0			
		Severe	0	0	0			
		Dyspepsia						
		Mild	2 (3.0%)	0	2 (2.1%)	4.0323 [0.1769, 91.9064]	3.6111 [0.1887, 69.0884] 0.2263	0.0399 [-0.0079, 0.0877]
		Moderate	0	0	0			
		Severe	0	0	0			
		Toothache						
		Mild	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.3750 [0.0223, 6.3181]	0.3878 [0.0255, 5.8905] 0.4836	-0.0213 [-0.0916, 0.0490]
		Moderate	0	0	0			
		Severe	0	0	0			
		Abdominal pain						
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 82 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>							
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Diarrhoea		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]	
		Moderate	0	0	0				
		Gastrointestinal motility disorder	Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)				
	Mild		1 (1.5%)	0	1 (1.0%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717] 0.4008	0.0200 [-0.0143, 0.0542]	
		Abdominal discomfort	Moderate	0	0	0			
			Severe	0	0	0			
			Abdominal	0	0	0			
		Abdominal pain upper	Mild	0	0	0			
			Moderate	0	0	0			
			Severe	0	0	0			
	Abdominal pain upper	Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 83 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropi n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR	RD
							[95 %-CI] <sup>b</sup>	p-value <sup>c</sup>
Gastrointestinal disorders	Aphthous ulcer		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Constipation		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastric disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Lip swelling		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Nausea		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vomiting		0	0	0			
Mild		0	0	0				
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 84 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>							
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropi n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders			4 (6.1%)	1 (3.2%)	5 (5.2%)				
		Mild	3 (4.5%)	1 (3.2%)	4 (4.1%)	1.3646 [0.1436, 12.9713]	1.3498 [0.1626, 11.2043]	0.0122 [-0.0711, 0.0954]	
		Moderate	1 (1.5%)	0	1 (1.0%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717]	0.0200 [-0.0143, 0.0542]	
		Severe	0	0	0		0.4008		
		Iron deficiency anaemia		3 (4.5%)	0	3 (3.1%)			
		Mild	2 (3.0%)	0	2 (2.1%)	1.6492 [0.1641, 16.5757]	1.6183 [0.1758, 14.8944]	0.0334 [-0.0106, 0.0775]	
		Moderate	1 (1.5%)	0	1 (1.0%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717]	0.0200 [-0.0143, 0.0542]	
		Severe	0	0	0		0.2981		
		Anaemia		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375]	-0.0348 [-0.0995, 0.0299]	
		Moderate	0	0	0		0.1083		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 85 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Blood and lymphatic system disorders	Neutropenia		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
	Lymphadenopathy	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	General disorders and administration site conditions	Severe	0	0	0			
			3 (4.5%)	2 (6.5%)	5 (5.2%)			
		Mild	3 (4.5%)	1 (3.2%)	4 (4.1%)	1.7004 [0.1509, 19.1585]	1.6592 [0.1508, 18.2490] 0.6777	0.0186 [-0.0592, 0.0965]
Moderate		0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 86 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions	Pyrexia		2 (3.0%)	1 (3.2%)	3 (3.1%)			
		Mild	2 (3.0%)	1 (3.2%)	3 (3.1%)	0.9533 [0.0721, 12.5981]	0.9533 [0.0609, 14.9229] 0.9727	-0.0013 [-0.0732, 0.0705]
		Moderate	0	0	0			
	Face oedema	Severe	0	0	0			
		Mild	0	1 (3.2%)	1 (1.0%)			
		Moderate	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]
	Gait disturbance	Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	2.2727 [0.0852, 60.6357]	2.1667 [0.0957, 49.0717] 0.4008	0.0200 [-0.0143, 0.0542]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 87 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions	Fatigue		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Influenza like illness	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Injection site atrophy	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Injection site swelling	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 88 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and site administration site conditions	Injection urticaria		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Medical device discomfort	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Vaccination site pain	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 89 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations			2 (3.0%)	2 (6.5%)	4 (4.1%)			
		Mild	2 (3.0%)	2 (6.5%)	4 (4.1%)	0.3617 [0.0472, 2.7732]	0.3878 [0.0588, 2.5591] 0.3144	-0.0426 [-0.1398, 0.0547]
		Moderate	0	0	0			
		Severe	0	0	0			
	Alanine aminotransferase increased		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Aspartate aminotransferase increased		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 90 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Blood cortisol decreased		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood iron increased		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375] 0.1083	-0.0348 [-0.0995, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cortisol free urine decreased		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 91 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Insulin-like growth factors increased		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood iron decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Blood thyroid stimulating hormone increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Eosinophil count increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 92 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Thyroxine decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Transaminases increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	White blood cell count decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 93 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders			2 (3.0%)	1 (3.2%)	3 (3.1%)			
		Mild	2 (3.0%)	1 (3.2%)	3 (3.1%)	0.9533 [0.0721, 12.5981]	0.9533 [0.0609, 14.9229] 0.9727	-0.0013 [-0.0732, 0.0705]
		Moderate	0	0	0			
	Arthritis reactive	Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
	Pain in extremity	Moderate	0	0	0			
		Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 94 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Synovial cyst		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524] 0.2340	-0.0283 [-0.0870, 0.0305]
		Moderate	0	0	0			
	Arthralgia	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Back pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Musculoskeletal pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 95 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Neck mass		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pain in jaw	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Nervous system disorders	Severe	0	0	0			
			2 (3.0%)	1 (3.2%)	3 (3.1%)			
		Mild	2 (3.0%)	1 (3.2%)	3 (3.1%)	0.7660 [0.0654, 8.9758]	0.7755 [0.0746, 8.0611]	-0.0078 [-0.0832, 0.0676]
Moderate		0	0	0		0.8326		
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 96 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders	Headache		2 (3.0%)	1 (3.2%)	3 (3.1%)			
		Mild	2 (3.0%)	1 (3.2%)	3 (3.1%)	0.7660 [0.0654, 8.9758]	0.7755 [0.0746, 8.0611] 0.8326	-0.0078 [-0.0832, 0.0676]
		Moderate	0	0	0			
	Dizziness	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Migraine	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Post-traumatic headache	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tremor	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 97 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders			1 (1.5%)	2 (6.5%)	3 (3.1%)			
		Mild	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.4766 [0.0238, 9.5351]	0.4766 [0.0189, 12.0087]	-0.0148 [-0.0805, 0.0509]
		Moderate	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.6452 0.1333 [0.0057, 3.1375]	-0.0348 [-0.0995, 0.0299]
	Dermatitis allergic	Severe	0	0	0		0.1083	
		Mild	0	1 (3.2%)	1 (1.0%)			
		Moderate	0	0	0			
	Petechiae	Severe	0	0	0			
		Mild	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524]	-0.0283 [-0.0870, 0.0305]
		Moderate	0	0	0		0.2340	
	Urticaria	Severe	0	0	0			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0		0.5335	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 98 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Urticaria	Moderate	0	1 (3.2%)	1 (1.0%)	0.1246 [0.0049, 3.1965]	0.1333 [0.0057, 3.1375]	-0.0348 [-0.0995, 0.0299]
		Severe	0	0	0			
	Cafe au lait spots	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		0.1083						
	Dermatitis contact	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eczema	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Keratosis pilaris	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 99 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR [95 %-CI] <sup>b</sup>	RR	RD [95 %-CI] <sup>b</sup>
			hGH (N=66)	n (N=31)			[95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Pityriasis alba		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Rash	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Rash erythematous	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Rash pruritic	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Immune system disorders			2 (3.0%)	0	2 (2.1%)			
		Mild	2 (3.0%)	0	2 (2.1%)	2.0526 [0.0942, 44.7416]	2.0000 [0.1004, 39.8412] 0.3749	0.0270 [-0.0129, 0.0668]
		Moderate	0	0	0			
	Allergy to animal	Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
	Seasonal allergy	Moderate	0	0	0			
		Severe	0	0	0			
			1 (1.5%)	0	1 (1.0%)			
	Hypersensitivity	Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 101 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>							
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropi n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Vascular disorders			2 (3.0%)	0	2 (2.1%)				
		Mild	2 (3.0%)	0	2 (2.1%)	2.0526 [0.0942, 44.7416]	2.0000 [0.1004, 39.8412] 0.3749	0.0270 [-0.0129, 0.0668]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Hypotension		2 (3.0%)	0	2 (2.1%)			
		Mild	2 (3.0%)	0	2 (2.1%)	2.0526 [0.0942, 44.7416]	2.0000 [0.1004, 39.8412] 0.3749	0.0270 [-0.0129, 0.0668]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Cardiac disorders			1 (1.5%)	0	1 (1.0%)			
			Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0				
		Severe	0	0	0				
		Sinoatrial block		1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>							
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropi n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Cardiac disorders	Tachycardia		1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]	
		Moderate	0	0	0				
	Sinus tachycardia	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Ear and labyrinth disorders			1 (1.5%)	0	1 (1.0%)			
		Mild		1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
			Moderate	0	0	0			
Severe			0	0	0				
Ear pain		Mild	1 (1.5%)	0	1 (1.0%)				
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]	
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			1 (1.5%)	0	1 (1.0%)			
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			
		Skin papilloma		1 (1.5%)	0	1 (1.0%)		
		Mild	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372] 0.5335	0.0135 [-0.0149, 0.0418]
		Moderate	0	0	0			
		Severe	0	0	0			
		Osteoma		0	0	0		
		Mild	0	0	0			
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Reproductive system and breast disorders			0	1 (3.2%)	1 (1.0%)				
		Mild	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524] 0.2340	-0.0283 [-0.0870, 0.0305]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Genital discomfort		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524] 0.2340	-0.0283 [-0.0870, 0.0305]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Penile adhesion		0	1 (3.2%)	1 (1.0%)			
		Mild	0	1 (3.2%)	1 (1.0%)	0.2190 [0.0082, 5.8561]	0.2407 [0.0106, 5.4524] 0.2340	-0.0283 [-0.0870, 0.0305]	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 105 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=66)	
Eye disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Astigmatism		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis allergic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye haemorrhage		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye swelling		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypermetropia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 106 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Eye disorders	Myopia	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Strabismus	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Hepatobiliary disorders		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatomegaly	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Metabolism and nutrition disorders		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 107 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=66)	Genotropin n (N=31)	Total (N=97)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Metabolism and nutrition disorders	Polydipsia		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
Psychiatric disorders			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Affect lability	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Attention deficit/hyperactivity disorder			0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 108 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Europe			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=66)		(N=31)
Psychiatric disorders	Depressive symptom		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Enuresis	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
	Renal and urinary disorders	Enuresis	Moderate	0	0	0			
			Severe	0	0	0			
				0	0	0			
		Pollakiuria	Mild	0	0	0			
			Moderate	0	0	0			
			Severe	0	0	0			
Polyuria			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 109 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Any adverse event			11 (91.7%)	6 (60.0%)	17 (77.3%)				
		Mild	10 (83.3%)	4 (40.0%)	14 (63.6%)	7.5333 [0.9894, 57.3585]	2.0538 [0.9279, 4.5458]	0.4242 [0.0547, 0.7938]	
		Moderate	1 (8.3%)	2 (20.0%)	3 (13.6%)	0.3750 [0.0272, 5.1688]	0.4444 [0.0491, 4.0250]	-0.1082 [-0.3960, 0.1795]	
		Severe	0	0	0		0.4670		
Infections and infestations			6 (50.0%)	3 (30.0%)	9 (40.9%)				
		Mild	6 (50.0%)	3 (30.0%)	9 (40.9%)	2.2985 [0.3793, 13.9294]	1.6170 [0.5506, 4.7486]	0.1883 [-0.2067, 0.5834]	
		Moderate	0	0	0		0.3849		
		Severe	0	0	0				
		Nasopharyngitis		3 (25.0%)	2 (20.0%)	5 (22.7%)			
		Mild	3 (25.0%)	2 (20.0%)	5 (22.7%)	1.2609 [0.1602, 9.9261]	1.1875 [0.2600, 5.4238]	0.0390 [-0.3049, 0.3829]	
	Moderate	0	0	0		0.8334			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropi n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pharyngitis		2 (16.7%)	1 (10.0%)	3 (13.6%)				
		Mild	2 (16.7%)	1 (10.0%)	3 (13.6%)	1.7250 [0.1364, 21.8190]	1.6444 [0.1522, 17.7628] 0.6849	0.0628 [-0.2210, 0.3466]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Upper respiratory tract infection			0	2 (20.0%)	2 (9.1%)			
		Mild	0	2 (20.0%)	2 (9.1%)	0.1368 [0.0056, 3.3439]	0.1800 [0.0099, 3.2705] 0.1213	-0.1948 [-0.4415, 0.0518]	
		Moderate	0	0	0				
		Severe	0	0	0				
	Eczema infected			1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 111 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropi n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Enterobiasis		1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
		Moderate	0	0	0			
	Infected bite	Severe	0	0	0			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
		Moderate	0	0	0			
	Pulpitis dental	Severe	0	0	0			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
		Moderate	0	0	0			
	Sinusitis	Severe	0	0	0			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Tonsillitis		1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
		Moderate	0	0	0			
	Viral upper respiratory tract infection	Severe	0	0	0			
			1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
	Appendicitis	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Atypical pneumonia	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Infections and infestations	Bronchitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Croup infectious		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cystitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 114 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Ear infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Enteritis infectious		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastroenteritis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastroenteritis viral		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Helminthic infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 115 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		
Infections and infestations	Hordeolum		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Influenza		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Laryngitis viral		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Molluscum contagiosum		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis externa		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 116 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Infections and infestations	Otitis media acute		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngitis streptococcal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngotonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pneumonia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 117 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		
Infections and infestations	Respiratory tract infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Respiratory tract infection viral		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rhinitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rotavirus infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tinea pedis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 118 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon Genotropi		Total (N=22)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=12)	n (N=10)		OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Tooth abscess		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Urinary tract infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Varicella		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Viral infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vulvitis		0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 119 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=12)	n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders			7 (58.3%)	1 (10.0%)	8 (36.4%)			
		Mild	7 (58.3%)	1 (10.0%)	8 (36.4%)	9.6800 [1.1304, 82.8927]	5.8222 [0.7737, 43.8143] 0.0248	0.4697 [0.1190, 0.8204]
		Moderate	0	0	0			
		Severe	0	0	0			
		Diarrhoea						
		Mild	3 (25.0%)	0	3 (13.6%)	4.3017 [0.3894, 47.5242]	3.1548 [0.4164, 23.9001] 0.1107	0.2468 [0.0018, 0.4917]
		Mild	3 (25.0%)	0	3 (13.6%)	4.3017 [0.3894, 47.5242]	3.1548 [0.4164, 23.9001] 0.1107	0.2468 [0.0018, 0.4917]
		Moderate	0	0	0			
		Severe	0	0	0			
		Vomiting						
		Mild	3 (25.0%)	0	3 (13.6%)	4.3017 [0.3894, 47.5242]	3.1548 [0.4164, 23.9001] 0.1107	0.2468 [0.0018, 0.4917]
		Moderate	0	0	0			
		Severe	0	0	0			
		Abdominal discomfort						
	Mild	2 (16.7%)	0	2 (9.1%)	5.6667 [0.2330, 137.7970]	4.5000 [0.2477, 81.7629] 0.1685	0.1732 [-0.0406, 0.3870]	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Abdominal pain		1 (8.3%)	1 (10.0%)	2 (9.1%)				
		Mild	1 (8.3%)	1 (10.0%)	2 (9.1%)	0.8750 [0.0457, 16.7443]	0.8889 [0.0658, 12.0044] 0.9314	-0.0108 [-0.2509, 0.2292]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Constipation	Mild	1 (8.3%)	0	1 (4.5%)			
			Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
			Moderate	0	0	0			
			Severe	0	0	0			
		Lip swelling	Mild	1 (8.3%)	0	1 (4.5%)			
			Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
			Moderate	0	0	0			
			Severe	0	0	0			
Nausea	Mild	1 (8.3%)	0	1 (4.5%)					
	Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]		
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Abdominal pain upper		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Aphthous ulcer	Severe	0	0	0			
	Mild		0	0	0				
	Moderate		0	0	0				
		Dyspepsia	Severe	0	0	0			
	Mild		0	0	0				
	Moderate		0	0	0				
		Gastric disorder	Severe	0	0	0			
	Mild		0	0	0				
	Moderate		0	0	0				
		Gastrointestinal motility disorder	Severe	0	0	0			
	Mild		0	0	0				
	Moderate		0	0	0				
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 122 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=22)		[95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Toothache		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
Eye disorders			3 (25.0%)	2 (20.0%)	5 (22.7%)				
		Mild	3 (25.0%)	2 (20.0%)	5 (22.7%)	1.5000	1.3333	0.0649	
						[0.1806, 12.4593]	[0.2932, 6.0639]	[-0.2694, 0.3993]	
							0.7150		
	Strabismus			0	0	0			
		Mild	1 (8.3%)	1 (10.0%)	2 (9.1%)	0.8750	0.8889	-0.0108	
						[0.0457, 16.7443]	[0.0658, 12.0044]	[-0.2509, 0.2292]	
							0.9314		
	Astigmatism			0	0	0			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000	2.7000	0.0866	
						[0.1064, 84.5581]	[0.1252, 58.2391]	[-0.0726, 0.2458]	
							0.3458		
			0	0	0				
			0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 123 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropi n (N=10)	Total (N=22)	RR		
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Eye disorders	Hypermetropia	Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
		Moderate	0	0	0			
		Severe	0	0	0			
	Myopia	Mild	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis allergic	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye haemorrhage	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye swelling	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 124 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and administrative site conditions			4 (33.3%)	1 (10.0%)	5 (22.7%)				
		Mild	4 (33.3%)	0	4 (18.2%)	5.7008 [0.5288, 61.4523]	3.7690 [0.5110, 27.8018] 0.0553	0.3333 [0.0660, 0.6007]	
		Moderate	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]	
		Severe	0	0	0				
		Pyrexia	Mild	4 (33.3%)	0	4 (18.2%)	5.7008 [0.5288, 61.4523]	3.7690 [0.5110, 27.8018] 0.0553	0.3333 [0.0660, 0.6007]
			Moderate	0	0	0			
			Severe	0	0	0			
		Fatigue	Mild	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
			Moderate	0	0	0			
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and like illness administration site conditions	Influenza		0	1 (10.0%)	1 (4.5%)			
		Mild	0	0	0			
		Moderate	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
	Injection site atrophy	Severe	0	0	0			
			1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
	Face oedema	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Gait disturbance	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and site administration site conditions	Injection site swelling	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site urticaria	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Medical device discomfort	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vaccination site pain	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 127 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=12)	n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations			3 (25.0%)	1 (10.0%)	4 (18.2%)			
		Mild	3 (25.0%)	1 (10.0%)	4 (18.2%)	2.9714 [0.2575, 34.2830]	2.5333 [0.2895, 22.1708] 0.3906	0.1494 [-0.1594, 0.4581]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eosinophil count increased		2 (16.7%)	0	2 (9.1%)			
		Mild	2 (16.7%)	0	2 (9.1%)	3.0000 [0.2554, 35.2324]	2.4464 [0.3054, 19.5975] 0.2132	0.1602 [-0.0485, 0.3689]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood iron decreased		0	1 (10.0%)	1 (4.5%)			
		Mild	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 128 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Thyroxine decreased		0	1 (10.0%)	1 (4.5%)			
		Mild	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
		Moderate	0	0	0			
	Transaminases increased	Severe	0	0	0			
			1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
	Alanine aminotransferase increased	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Investigations	Aspartate aminotransferase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood cortisol decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood iron increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood thyroid stimulating hormone increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			(N=12)	
Investigations	Cortisol free urine decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Insulin-like growth factor increased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	White blood cell count decreased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 131 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropi n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders			3 (25.0%)	1 (10.0%)	4 (18.2%)			
		Mild	3 (25.0%)	1 (10.0%)	4 (18.2%)	2.5750 [0.2593, 25.5750]	2.4000 [0.2427, 23.7345] 0.4151	0.1364 [-0.1805, 0.4532]
		Moderate	0	0	0			
		Severe	0	0	0			
		Cough						
		Mild	2 (16.7%)	0	2 (9.1%)	3.0000 [0.2554, 35.2324]	2.4464 [0.3054, 19.5975] 0.2132	0.1602 [-0.0485, 0.3689]
		Moderate	0	0	0			
		Severe	0	0	0			
		Wheezing						
		Mild	1 (8.3%)	1 (10.0%)	2 (9.1%)	0.8750 [0.0457, 16.7443]	0.8889 [0.0658, 12.0044] 0.9314	-0.0108 [-0.2509, 0.2292]
		Moderate	0	0	0			
		Severe	0	0	0			
	Epistaxis							
	Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		0	1 (10.0%)	1 (4.5%)			
		Mild	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
		Moderate	0	0	0			
	Allergic cough	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Asthma	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Dyspnoea exertional	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Laryngospasm		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Nasal congestion	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Paranasal sinus discomfort	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Respiratory disorder	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Sinus congestion	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Sleep apnoea syndrome	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Endocrine disorders	Severe	0	0	0			
		Mild	2 (16.7%)	1 (10.0%)	3 (13.6%)			
		Mild	1 (8.3%)	1 (10.0%)	2 (9.1%)	0.8750 [0.0457, 16.7443]	0.8889 [0.0658, 12.0044] 0.9314	-0.0108 [-0.2509, 0.2292]

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Adrenal insufficiency	Moderate	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]	
		Severe	0	0	0				
	Secondary adrenocortical insufficiency	Mild	0	0	0				
		Moderate	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]	
	Secondary adrenocortical insufficiency	Severe	0	0	0				
		Mild	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]	
	Secondary hypothyroidism	Moderate	Severe	0	0	0			
			Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
		Severe	Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropi n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders	Diabetes insipidus		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypothyroidism			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Injury, poisoning and procedural complications			3 (25.0%)	0	3 (13.6%)			
		Mild		3 (25.0%)	0	3 (13.6%)	4.3017 [0.3894, 47.5242]	3.1548 [0.4164, 23.9001] 0.1107	0.2468 [0.0018, 0.4917]
Moderate				0	0	0			
Severe				0	0	0			
Arthropod bite				1 (8.3%)	0	1 (4.5%)			
		Mild		1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
			Moderate		0	0	0		
			Severe		0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Contusion		1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
		Moderate	0	0	0			
	Fall	Severe	0	0	0			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
		Moderate	0	0	0			
	Laceration	Severe	0	0	0			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.1064, 84.5581]	2.7000 [0.1252, 58.2391] 0.3458	0.0866 [-0.0726, 0.2458]
		Moderate	0	0	0			
	Animal bite	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and fracture procedural complications	Ankle		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Burns first degree	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Burns second degree	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Concussion	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Face injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 139 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Head injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Ligament sprain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Meniscus injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Muscle strain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Post-traumatic pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 140 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Radius fracture		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Thermal burn		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Upper limb fracture		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Wrist fracture		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 141 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World		Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropi n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders			2 (16.7%)	1 (10.0%)	3 (13.6%)			
		Mild	2 (16.7%)	0	2 (9.1%)	3.0000 [0.2554, 35.2324]	2.4464 [0.3054, 19.5975] 0.2132	0.1602 [-0.0485, 0.3689]
		Moderate	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
		Severe	0	0	0			
	Headache		2 (16.7%)	1 (10.0%)	3 (13.6%)			
		Mild	2 (16.7%)	0	2 (9.1%)	3.0000 [0.2554, 35.2324]	2.4464 [0.3054, 19.5975] 0.2132	0.1602 [-0.0485, 0.3689]
		Moderate	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
		Severe	0	0	0			
	Dizziness		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Migraine		0	0	0				
	Mild	0	0	0				
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 142 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	RR			
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Nervous system disorders	Post-traumatic headache		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Tremor	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Ear and labyrinth disorders		Severe	0	0	0			
				2 (16.7%)	0	2 (9.1%)			
			Mild	2 (16.7%)	0	2 (9.1%)	5.6667 [0.2330, 137.7970]	4.5000 [0.2477, 81.7629] 0.1685	0.1732 [-0.0406, 0.3870]
Ear pain		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	2 (16.7%)	0	2 (9.1%)	5.6667 [0.2330, 137.7970]	4.5000 [0.2477, 81.7629] 0.1685	0.1732 [-0.0406, 0.3870]	
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders			1 (8.3%)	1 (10.0%)	2 (9.1%)				
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]	
		Moderate	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]	
		Severe	0	0	0				
		Dermatitis contact		1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Rash pruritic		0	1 (10.0%)	1 (4.5%)			
		Mild	0	0	0				
		Moderate	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]	
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Cafe au lait spots		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis allergic			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Eczema			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Keratosis pilaris			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Petechiae			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 145 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>			
Skin and subcutaneous tissue disorders	Pityriasis alba		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Rash	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Rash erythematous	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Urticaria	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
			Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 146 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Blood and lymphatic system disorders			1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
		Moderate	0	0	0			
		Severe	0	0	0			
		Anaemia						
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
		Moderate	0	0	0			
		Severe	0	0	0			
		Iron deficiency anaemia						
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Lymphadenopathy							
	Mild	0	0	0				
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropi n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Blood and lymphatic system disorders	Neutropenia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Hepatobiliary disorders	Hepatomegaly		0	1 (10.0%)	1 (4.5%)			
		Mild	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]
		Moderate	0	0	0			
		Severe	0	0	0			
	Mild	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710] 0.2888	-0.0974 [-0.2817, 0.0869]	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Pain in extremity		0	1 (10.0%)	1 (4.5%)			
		Mild	0	1 (10.0%)	1 (4.5%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1104 [-0.3037, 0.0829]
		Moderate	0	0	0			
	Pain in extremity	Severe	0	0	0			
			0	1 (10.0%)	1 (4.5%)			
		Mild	0	1 (10.0%)	1 (4.5%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1104 [-0.3037, 0.0829]
	Arthralgia	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Arthritis reactive	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 149 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Back pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Musculoskeletal pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck mass	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Pain in jaw	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 150 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=12)	Genotropin n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Synovial cyst		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Psychiatric disorders	Enuresis		1 (8.3%)	0	1 (4.5%)			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0736 [-0.0752, 0.2224]
		Moderate	0	0	0			
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 151 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>			
Psychiatric disorders	Affect lability		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Attention deficit/hyperactivity disorder		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Depressive symptom		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Cardiac disorders			0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 152 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=12)		(N=10)
Cardiac disorders	Sinoatrial block		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
	Sinus tachycardia		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Tachycardia	Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
	Severe		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
Immune system disorders		Severe	0	0	0				
			Mild	0	0	0			
			Moderate	0	0	0			
	Allergy to animal	Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Severe		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 153 of 157



Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			(N=22)		[95 %-CI] <sup>b</sup>
			(N=12)	(N=10)		[95 %-CI] <sup>b</sup>			
Immune system disorders	Hypersensitivity		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Seasonal allergy	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
	Metabolism and nutrition disorders	Polydipsia	Moderate	0	0	0			
			Severe	0	0	0			
				0	0	0			
Polydipsia		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 154 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World

System Organ Class	Preferred Term	Severity	TransCon Genotropi			Lonapegsomatropin vs. Genotropina <sup>a</sup>		
			hGH (N=12)	n (N=10)	Total (N=22)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Osteoma	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Skin papilloma	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Renal and urinary disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 155 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD
			hGH	n			[95 %-CI] <sup>b</sup>	
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>		[95 %-CI] <sup>b</sup>
Renal and urinary disorders	Pollakiuria		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Polyuria	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
Reproductive system and breast disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Genital discomfort		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 156 of 157

Table 1.33 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by region  
Safety Population

Rest of the World			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon	Genotropi	Total	OR	RR	RD	
			hGH	n			[95 %-CI] <sup>b</sup>		p-value <sup>c</sup>
			(N=12)	(N=10)	(N=22)	[95 %-CI] <sup>b</sup>			
Reproductive system and breast disorders	Penile adhesion		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
Vascular disorders			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Hypotension			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 157 of 157

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>					Subgroup Interaction p-value	
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>		RD [95 %-CI] <sup>b</sup>
Any adverse event			60 (78.9%)	30 (73.2%)	90 (76.9%)				
		Mild	40 (52.6%)	15 (36.6%)	55 (47.0%)	1.9246 [0.8829, 4.1951]	1.4375 [0.9114, 2.2674]	0.1601 [-0.0251, 0.3454]	0.8259
		Moderate	19 (25.0%)	15 (36.6%)	34 (29.1%)	0.5779 [0.2537, 1.3166]	0.6852 [0.3920, 1.1977]	-0.1151 [-0.2912, 0.0611]	0.4733
		Severe	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
Infections and infestations			41 (53.9%)	23 (56.1%)	64 (54.7%)				
		Mild	27 (35.5%)	13 (31.7%)	40 (34.2%)	1.1850 [0.5286, 2.6564]	1.1195 [0.6513, 1.9243]	0.0379 [-0.1408, 0.2167]	0.8819
		Moderate	13 (17.1%)	10 (24.4%)	23 (19.7%)	0.6415 [0.2526, 1.6290]	0.7042 [0.3388, 1.4635]	-0.0719 [-0.2277, 0.0839]	0.7458
		Severe	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 1 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pharyngitis		8 (10.5%)	8 (19.5%)	16 (13.7%)				
		Mild	7 (9.2%)	8 (19.5%)	15 (12.8%)	0.4114 [0.1347, 1.2565]	0.4770 [0.1893, 1.2019]	-0.1018 [-0.2375, 0.0340]	0.9065
		Moderate	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	0.1151 1.7647 [0.0792, 39.3233]	0.0135 [-0.0124, 0.0395]	0.9808
	Nasopharyngitis	Severe	0	0	0		0.4533		
			10 (13.2%)	5 (12.2%)	15 (12.8%)				
		Mild	9 (11.8%)	4 (9.8%)	13 (11.1%)	1.2378 [0.3617, 4.2359]	1.2140 [0.3960, 3.7215]	0.0210 [-0.0967, 0.1386]	0.2184
	Respiratory tract infection	Moderate	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5435 [0.0338, 8.7365]	0.7330 0.5435 [0.0328, 9.0180]	-0.0110 [-0.0648, 0.0428]	0.9988
		Severe	0	0	0		0.6657		
			5 (6.6%)	3 (7.3%)	8 (6.8%)				
		Mild	3 (3.9%)	2 (4.9%)	5 (4.3%)	0.8156 [0.1345, 4.9440]	0.8187 [0.1412, 4.7453]	-0.0089 [-0.0894, 0.0716]	0.9694

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>				
Infections and infestations	Respiratory tract infection	Moderate	2 (2.6%)	1 (2.4%)	3 (2.6%)	1.0870	1.0870	0.0021	0.9998	[0.0970, 12.1741]	[0.0957, 12.3405]	[-0.0577, 0.0619]			
		Severe	0	0	0								0.9462		
		Gastroenteritis	3 (3.9%)	3 (7.3%)	6 (5.1%)										
	Upper respiratory tract infection	Mild	3 (3.9%)	2 (4.9%)	5 (4.3%)	0.8026	0.8075	-0.0093	0.9996	[0.1298, 4.9604]	[0.1369, 4.7620]	[-0.0889, 0.0702]			
		Moderate	0	1 (2.4%)	1 (0.9%)	0.1736	0.1803	-0.0245	0.9743	[0.0069, 4.3850]	[0.0076, 4.3037]	[-0.0718, 0.0228]			
		Severe	0	0	0										
		Mild	2 (2.6%)	4 (9.8%)	6 (5.1%)										
		Mild	2 (2.6%)	3 (7.3%)	5 (4.3%)	0.3333	0.3556	-0.0473	0.9748	[0.0527, 2.1070]	[0.0626, 2.0196]	[-0.1344, 0.0398]			
		Moderate	0	1 (2.4%)	1 (0.9%)	0.1736	0.1803	-0.0245	0.9983	[0.0069, 4.3850]	[0.0076, 4.3037]	[-0.0718, 0.0228]			
	Severe	0	0	0											

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Viral infection		6 (7.9%)	0	6 (5.1%)				
		Mild	5 (6.6%)	0	5 (4.3%)	3.6168 [0.4136, 31.6287]	3.3376 [0.4194, 26.5628]	0.0662 [0.0103, 0.1221]	0.9713
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
	Ear infection	Severe	0	0	0		0.0937		
		Mild	4 (5.3%)	1 (2.4%)	5 (4.3%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9988
		Moderate	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.6496	0.6496		
	Rhinitis	Moderate	3 (3.9%)	0	3 (2.6%)	2.2945 [0.2427, 21.6970]	2.1997 [0.2538, 19.0657]	0.0396 [-0.0042, 0.0835]	0.9996
		Severe	0	0	0		0.2002		
		Mild	3 (3.9%)	2 (4.9%)	5 (4.3%)	0.8152 [0.1353, 4.9123]	0.8152 [0.1332, 4.9902]	-0.0089 [-0.0893, 0.0715]	0.9730
		Moderate	3 (3.9%)	2 (4.9%)	5 (4.3%)		0.8221		
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 4 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Bronchitis		2 (2.6%)	2 (4.9%)	4 (3.4%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233]	0.0135 [-0.0124, 0.0395]	0.9981
		Moderate	1 (1.3%)	2 (4.9%)	3 (2.6%)	0.2556 [0.0211, 3.1018]	0.4533 0.2786 [0.0276, 2.8141]	-0.0350 [-0.1049, 0.0348]	0.9705
	Enteritis infectious	Severe	0	0	0		0.2542		
		Mild	1 (1.3%)	2 (4.9%)	3 (2.6%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	2 (4.9%)	2 (1.7%)	0.1727 [0.0171, 1.7396]	0.4652 0.1882 [0.0205, 1.7305]	-0.0485 [-0.1143, 0.0173]	0.9757
	Gastroenteritis viral	Severe	0	0	0		0.0560		
		Mild	3 (3.9%)	0	3 (2.6%)	2.2945 [0.2427, 21.6970]	2.1997 [0.2538, 19.0657]	0.0396 [-0.0042, 0.0835]	0.9778
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 5 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Pharyngitis streptococcal		3 (3.9%)	0	3 (2.6%)				
		Mild	2 (2.6%)	0	2 (1.7%)	2.7778 [0.1294, 59.6290]	2.7049 [0.1338, 54.6938]	0.0261 [-0.0097, 0.0620]	0.9422
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9502
	Pneumonia	Severe	0	0	0		0.2990		
		Mild	1 (1.3%)	2 (4.9%)	3 (2.6%)		1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9502
		Moderate	1 (1.3%)	2 (4.9%)	3 (2.6%)	0.2760 [0.0251, 3.0360]	0.2760 [0.0259, 2.9397]	-0.0355 [-0.1071, 0.0362]	0.9969
	Respiratory tract infection viral	Severe	0	0	0		0.2518		
		Mild	2 (2.6%)	1 (2.4%)	3 (2.6%)		0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9747
		Moderate	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9747

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Infections and infestations	Respiratory tract infection viral	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808				
		Severe	0	0	0	0.4652							
		Helminthic infection	1 (1.3%)	1 (2.4%)	2 (1.7%)								
	Helminthic infection	Mild	0	0	0								
		Moderate	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9988				
		Severe	0	0	0	0.6496							
	Influenza	Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743				
		Moderate	0	1 (2.4%)	1 (0.9%)								
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808				
		Severe	0	0	0	0.4652							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 7 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Otitis media acute		1 (1.3%)	1 (2.4%)	2 (1.7%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.4652 0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743
	Pharyngotonsillitis	Severe	0	0	0		0.1709		
			1 (1.3%)	1 (2.4%)	2 (1.7%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743
	Sinusitis	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0		0.4652		
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9728

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 8 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Sinusitis	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9981
		Severe	0	0	0	0.4652			
	Viral upper respiratory tract infection	Severe	1 (1.3%)	1 (2.4%)	2 (1.7%)				0.9988
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	
		Moderate	0	0	0	0.6496			
	Appendicitis	Severe	0	0	0				0.9808
		Mild	1 (1.3%)	0	1 (0.9%)				
		Moderate	0	0	0				
		Severe	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	
	Atypical pneumonia	Severe	1 (1.3%)	0	1 (0.9%)	0.4652			
Mild		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 9 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Atypical pneumonia	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0	0.4652			
	Conjunctivitis	Mild	0	0	0				0.9725
		Moderate	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233]	0.0135 [-0.0124, 0.0395]	0.9808
	Conjunctivitis bacterial	Severe	0	0	0	0.4533			
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743
	Croup infectious	Moderate	0	0	0				
		Severe	0	0	0				
		Mild	0	1 (2.4%)	1 (0.9%)				
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 10 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Cystitis		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
	Eczema infected		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
	Enterobiasis		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9787
		Moderate	0	0	0				
		Severe	0	0	0				
Hordeolum		0	1 (2.4%)	1 (0.9%)					
	Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 11 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Infected bite		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
	Laryngitis viral	Severe	0	0	0				
			0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1717 [0.0063, 4.6830]	0.1961 [0.0088, 4.3693] 0.1824	-0.0240 [-0.0709, 0.0229]	0.9743
	Otitis externa	Moderate	0	0	0				
		Severe	0	0	0				
			1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 12 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Infections and infestations	Pulpitis dental		1 (1.3%)	0	1 (0.9%)					
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808	
		Moderate	0	0	0					
		Rotavirus infection	Severe	0	0	0				
				1 (1.3%)	0	1 (0.9%)				
	Mild		1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808	
			Moderate	0	0	0				
			Severe	0	0	0				
		Tonsillitis		0	1 (2.4%)	1 (0.9%)				
			Mild	0	0	0				0.9725
			Moderate	0	1 (2.4%)	1 (0.9%)	0.1717 [0.0063, 4.6830]	0.1961 [0.0088, 4.3693] 0.1824	-0.0240 [-0.0709, 0.0229]	0.9743
			Severe	0	0	0				
	Vulvitis		1 (1.3%)	0	1 (0.9%)					
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 13 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Infections and infestations	Molluscum contagiosum		0	0	0				
		Mild	0	0	0				0.9725
		Moderate	0	0	0				
	Tinea pedis	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9725
		Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				
	Tooth abscess	Mild	0	0	0				0.9725
		Moderate	0	0	0				
		Severe	0	0	0				
	Urinary tract infection		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9750
	Severe	0	0	0					
		0	0	0					
	Mild	0	0	0				0.9725	
Varicella	Moderate	0	0	0				0.9725	
	Severe	0	0	0					
		0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 14 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders			19 (25.0%)	4 (9.8%)	23 (19.7%)				
		Mild	13 (17.1%)	4 (9.8%)	17 (14.5%)	1.8847 [0.5800, 6.1243]	1.7520 [0.6077, 5.0507]	0.0737 [-0.0519, 0.1993]	0.9400
		Moderate	6 (7.9%)	0	6 (5.1%)	3.7093 [0.4151, 33.1480]	3.4026 [0.4147, 27.9202]	0.0788 [0.0182, 0.1394]	0.9734
		Severe	0	0	0		0.2850	0.0671	
		Cough	8 (10.5%)	1 (2.4%)	9 (7.7%)				
		Mild	7 (9.2%)	1 (2.4%)	8 (6.8%)	3.9886 [0.4887, 32.5503]	3.7893 [0.4825, 29.7567]	0.0683 [-0.0128, 0.1495]	0.1595
		Moderate	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233]	0.0135 [-0.0124, 0.0395]	0.9592
		Severe	0	0	0		0.1652	0.4533	
		Respiratory disorder	3 (3.9%)	1 (2.4%)	4 (3.4%)				
		Mild	2 (2.6%)	1 (2.4%)	3 (2.6%)	1.0868 [0.0974, 12.1232]	1.0853 [0.1018, 11.5743]	0.0021 [-0.0578, 0.0619]	0.9998

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 15 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9592				
		Severe	0	0	0	0.4652							
		Epistaxis	2 (2.6%)	1 (2.4%)	3 (2.6%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9789				
	Nasal congestion	Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808				
		Severe	0	0	0	0.4652							
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9988				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808				
		Severe	0	0	0	0.4652							
		Severe	0	0	0	0.4652							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 16 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76) Genotropin (N=41) Total (N=117)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Respiratory, thoracic and mediastinal disorders	Wheezing		2 (2.6%)	1 (2.4%)	3 (2.6%)				
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9988
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
	Rhinorrhoea	Severe	0	0	0		0.6496		
		Mild	0	2 (4.9%)	2 (1.7%)	0.1008 [0.0047, 2.1664]	0.1082 [0.0054, 2.1878]	-0.0490 [-0.1150, 0.0171]	0.9757
		Moderate	0	0	0		0.0515		
	Allergic cough	Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0		0.4652		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 17 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional		1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	Laryngospasm	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
	Paranasal sinus discomfort	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 18 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76) Genotropin (N=41) Total (N=117)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9787
		Moderate	0	0	0				
	Sinus congestion	Severe	0	0	0				
			1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				0.9741
	Sleep apnoea syndrome	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				
			1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 19 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Respiratory, thoracic and mediastinal disorders	Asthma		0	0	0								
		Mild	0	0	0						0.9725		
		Moderate	0	0	0						0.9988		
		Severe	0	0	0								
Gastrointestinal disorders			17 (22.4%)	5 (12.2%)	22 (18.8%)								
		Mild	16 (21.1%)	4 (9.8%)	20 (17.1%)	2.4647 [0.7620, 7.9717]	2.1473 [0.7719, 5.9738]	0.1124 [-0.0164, 0.2412]	0.8679				
		Moderate	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9716				
		Severe	0	0	0		0.1253 [0.0345, 8.2465]	0.6496					
	Vomiting	Mild	8 (10.5%)	2 (4.9%)	10 (8.5%)	4.7192 [0.5654, 39.3881]	4.2853 [0.5588, 32.8628]	0.0805 [-0.0029, 0.1638]	0.2152				
		Moderate	8 (10.5%)	1 (2.4%)	9 (7.7%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743				
		Severe	0	1 (2.4%)	1 (0.9%)		0.1206	0.1709					
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Gastrointestinal disorders	Diarrhoea		4 (5.3%)	2 (4.9%)	6 (5.1%)				
		Mild	4 (5.3%)	2 (4.9%)	6 (5.1%)	1.0714 [0.1854, 6.1925]	1.0667 [0.2064, 5.5113] 0.9389	0.0033 [-0.0790, 0.0855]	0.9776
		Moderate	0	0	0				
	Abdominal pain	Severe	0	0	0				
			3 (3.9%)	1 (2.4%)	4 (3.4%)				
		Mild	2 (2.6%)	1 (2.4%)	3 (2.6%)	1.0690 [0.0932, 12.2611]	1.0667 [0.1005, 11.3174] 0.9575	0.0016 [-0.0575, 0.0608]	0.9998
	Nausea	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				
			3 (3.9%)	1 (2.4%)	4 (3.4%)				
		Mild	2 (2.6%)	1 (2.4%)	3 (2.6%)	1.0690 [0.0932, 12.2611]	1.0667 [0.1005, 11.3174] 0.9575	0.0016 [-0.0575, 0.0608]	0.9777
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9592
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 21 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76) Genotropin (N=41) Total (N=117)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Gastrointestinal disorders	Abdominal pain upper	Mild	2 (2.6%)	1 (2.4%)	3 (2.6%)	1.0690 [0.0932, 12.2611]	1.0667 [0.1005, 11.3174] 0.9575	0.0016 [-0.0575, 0.0608]	0.9777
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal discomfort	Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9981
		Moderate	0	0	0				
		Severe	0	0	0				
	Aphthous ulcer	Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				
	Constipation	Mild	1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				0.9741

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 22 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Gastrointestinal disorders	Constipation	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808	
		Severe	0	0	0					
		Dyspepsia	1 (1.3%)	0	1 (0.9%)					
		Mild		1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9981
			Moderate	0	0	0				
			Severe	0	0	0				
	Gastric disorder	Mild		1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
			Moderate	0	0	0				
			Severe	0	0	0				
	Gastrointestinal motility disorder	Mild		1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value	
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Gastrointestinal disorders	Lip swelling		1 (1.3%)	0	1 (0.9%)					
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808	
		Moderate	0	0	0					
	Toothache	Severe	0	0	0					
		Mild	0	0	0				0.9988	
		Moderate	0	0	0					
	General disorders and administrative site conditions			16 (21.1%)	6 (14.6%)	22 (18.8%)				
		Mild		13 (17.1%)	4 (9.8%)	17 (14.5%)	1.9123 [0.5803, 6.3009]	1.7555 [0.6117, 5.0381] 0.2850	0.0737 [-0.0505, 0.1978]	0.0548
Moderate			3 (3.9%)	2 (4.9%)	5 (4.3%)	0.7895 [0.1250, 4.9859]	0.8000 [0.1408, 4.5442] 0.8022	-0.0098 [-0.0885, 0.0689]	0.9730	
Severe			0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 24 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and administrative site conditions	Pyrexia		14 (18.4%)	3 (7.3%)	17 (14.5%)				
		Mild	11 (14.5%)	3 (7.3%)	14 (12.0%)	2.1423 [0.5623, 8.1621]	1.9803 [0.5834, 6.7220]	0.0716 [-0.0408, 0.1839]	0.1231
		Moderate	3 (3.9%)	0	3 (2.6%)	3.9565 [0.1981, 79.0126]	3.7869 [0.2017, 71.1156]	0.0392 [-0.0044, 0.0828]	0.9996
	Fatigue	Severe	0	0	0		0.2593 0.2009		
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9988
		Moderate	0	0	0		0.6496		
	Face oedema	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743
		Severe	0	0	0		0.1709		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 25 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and administrative site conditions	Gait disturbance		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
		Moderate	0	0	0				
	Influenza like illness	Severe	0	0	0				
			0	1 (2.4%)	1 (0.9%)				
		Mild	0	0	0				
	Injection site atrophy	Moderate	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 26 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
General disorders and administration site conditions	Injection site urticaria		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
	Medical device discomfort		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				
	Vaccination site pain		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 27 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
General disorders and administration site conditions	Injection site swelling		0	0	0								
		Mild	0	0	0							0.9750	
		Moderate	0	0	0								
		Severe	0	0	0								
Nervous system disorders	Headache		8 (10.5%)	7 (17.1%)	15 (12.8%)								
		Mild	5 (6.6%)	5 (12.2%)	10 (8.5%)	0.5040 [0.1374, 1.8493]	0.5371 [0.1658, 1.7402]	-0.0567 [-0.1714, 0.0580]	0.2967		0.1866		
		Moderate	3 (3.9%)	2 (4.9%)	5 (4.3%)	0.7895 [0.1250, 4.9859]	0.8000 [0.1408, 4.5442]	-0.0098 [-0.0885, 0.0689]	0.8022		0.7846		
		Severe	0	0	0								
		Mild	5 (6.6%)	4 (9.8%)	9 (7.7%)	0.6479 [0.1644, 2.5535]	0.6713 [0.1915, 2.3534]	-0.0322 [-0.1388, 0.0744]	0.5345		0.9721		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Nervous system disorders	Headache	Moderate	3 (3.9%)	2 (4.9%)	5 (4.3%)	0.7895 [0.1250, 4.9859]	0.8000 [0.1408, 4.5442]	-0.0098 [-0.0885, 0.0689]	0.7846
		Severe	0	0	0		0.8022		
	Dizziness	Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9789
		Moderate	0	0	0		0.6496		
	Migraine	Severe	0	0	0				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0		0.1709		
		Severe	0	0	0				
	Post-traumatic headache	Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9592
		Moderate	0	0	0		0.4652		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 29 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Nervous system disorders	Tremor		1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
Injury, poisoning and procedural complications	Post-traumatic pain	Severe	0	0	0				
			8 (10.5%)	5 (12.2%)	13 (11.1%)				
		Mild	5 (6.6%)	4 (9.8%)	9 (7.7%)	0.6364 [0.1583, 2.5582]	0.6667 [0.1924, 2.3102]	-0.0327 [-0.1381, 0.0727]	0.3642
		Moderate	3 (3.9%)	1 (2.4%)	4 (3.4%)	1.6316 [0.1628, 16.3561]	1.6000 [0.1734, 14.7632] 0.6761	0.0147 [-0.0494, 0.0788]	0.9730
		Severe	0	0	0				
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465] 0.6496	-0.0114 [-0.0651, 0.0422]	0.9988
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 30 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Injury, poisoning and procedural complications	Animal bite		0	1 (2.4%)	1 (0.9%)					
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9540	
		Moderate	0	0	0					
		Severe	0	0	0					
		Ankle fracture		1 (1.3%)	0	1 (0.9%)				
			Mild	0	0	0				
			Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
			Severe	0	0	0				
		Arthropod bite		0	1 (2.4%)	1 (0.9%)				
			Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9540
			Moderate	0	0	0				
			Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 31 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Concussion		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
	Contusion	Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)				0.9725
		Moderate	0	0	0				
	Face injury	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	Head injury	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 32 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Laceration		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
	Ligament sprain	Severe	0	0	0				
			1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	Meniscus injury	Moderate	0	0	0				
		Severe	0	0	0				
			0	1 (2.4%)	1 (0.9%)				
		Mild	0	0	0				
		Moderate	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 33 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Injury, poisoning and procedural complications	Radius fracture		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
	Thermal burn	Severe	0	0	0				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
	Upper limb fracture	Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 34 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	RD [95 %-CI] <sup>b</sup>								
Injury, poisoning and procedural complications	Burns first degree		0	0	0							0.9750	
		Mild	0	0	0								
		Moderate	0	0	0								
	Burns second degree		0	0	0							0.9725	
		Mild	0	0	0								
		Moderate	0	0	0								
	Fall		0	0	0							0.9725	
		Mild	0	0	0								
		Moderate	0	0	0								
	Muscle strain		0	0	0							0.9725	
		Mild	0	0	0								
		Moderate	0	0	0								
	Wrist fracture		0	0	0							0.9725	
		Mild	0	0	0								
		Moderate	0	0	0								
			Severe	0	0	0							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 35 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Organ Preferred Term	Severity	TransCon hGH (N=76) Genotropin (N=41) Total (N=117)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Musculoskeletal and connective tissue disorders			8 (10.5%)	4 (9.8%)	12 (10.3%)				
		Mild	6 (7.9%)	4 (9.8%)	10 (8.5%)	0.7878 [0.2090, 2.9692]	0.8038 [0.2389, 2.7041]	-0.0191 [-0.1284, 0.0901]	0.6908
		Moderate	2 (2.6%)	0	2 (1.7%)	2.7778 [0.1294, 59.6290]	2.7049 [0.1338, 54.6938]	0.0261 [-0.0097, 0.0620]	0.9728
		Severe	0	0	0		0.7246 0.2990		
		Pain in extremity	4 (5.3%)	2 (4.9%)	6 (5.1%)				
		Mild	3 (3.9%)	2 (4.9%)	5 (4.3%)	0.7895 [0.1250, 4.9859]	0.8000 [0.1408, 4.5442]	-0.0098 [-0.0885, 0.0689]	0.9714
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0		0.8022 0.4652		
		Arthralgia	3 (3.9%)	1 (2.4%)	4 (3.4%)				
		Mild	3 (3.9%)	1 (2.4%)	4 (3.4%)	1.6316 [0.1628, 16.3561]	1.6000 [0.1734, 14.7632]	0.0147 [-0.0494, 0.0788]	0.9730
	Moderate	0	0	0		0.6761			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76) Genotropin (N=41) Total (N=117)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Musculoskeletal and connective tissue disorders	Musculoskeletal pain		2 (2.6%)	0	2 (1.7%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	Neck pain	Severe	0	0	0				
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465] 0.6496	-0.0114 [-0.0651, 0.0422]	0.9988
		Moderate	0	0	0				
	Arthritis reactive	Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 37 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Back pain		1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	Neck mass	Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
	Pain in jaw	Severe	0	0	0				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 38 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Organ Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Synovial cyst		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1717 [0.0063, 4.6830]	0.1961 [0.0088, 4.3693] 0.1824	-0.0240 [-0.0709, 0.0229]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				
Skin and subcutaneous tissue disorders			7 (9.2%)	4 (9.8%)	11 (9.4%)				
		Mild	6 (7.9%)	2 (4.9%)	8 (6.8%)	1.7009 [0.3229, 8.9602]	1.6339 [0.3475, 7.6831] 0.5320	0.0308 [-0.0581, 0.1196]	0.9781
		Moderate	1 (1.3%)	2 (4.9%)	3 (2.6%)	0.2542 [0.0222, 2.9179]	0.2667 [0.0251, 2.8294] 0.2410	-0.0359 [-0.1066, 0.0347]	0.9969
	Rash	Severe	0	0	0				
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)				
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465] 0.6496	-0.0114 [-0.0651, 0.0422]	0.9748
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Urticaria		1 (1.3%)	1 (2.4%)	2 (1.7%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.4652 0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743
	Cafe au lait spots	Severe	0	0	0		0.1709		
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233]	0.0135 [-0.0124, 0.0395]	0.9808
		Moderate	0	0	0		0.4533		
	Dermatitis allergic	Severe	0	0	0				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1717 [0.0063, 4.6830]	0.1961 [0.0088, 4.3693]	-0.0240 [-0.0709, 0.0229]	0.9743
		Moderate	0	0	0		0.1824		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 40 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Dermatitis contact		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
		Moderate	0	0	0				
	Eczema	Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	Keratosis pilaris	Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 41 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Petechiae		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
	Pityriasis alba	Severe	0	0	0				
			1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
	Rash erythematous	Moderate	0	0	0				
		Severe	0	0	0				
			1 (1.3%)	0	1 (0.9%)				
	Rash pruritic	Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
		0	1 (2.4%)	1 (0.9%)					
	Mild	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 42 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction n p-value
Skin and subcutaneous tissue disorders	Rash pruritic	Moderate	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743
		Severe	0	0	0		0.1709		
Endocrine disorders	Secondary hypothyroidism	Mild	6 (7.9%)	4 (9.8%)	10 (8.5%)				
		Moderate	0	0	0				
		Severe	0	0	0				
		Mild	6 (7.9%)	4 (9.8%)	10 (8.5%)	0.7878 [0.2090, 2.9692]	0.8038 [0.2389, 2.7041]	-0.0191 [-0.1284, 0.0901]	0.3935
		Moderate	0	0	0		0.7246		0.9741
		Severe	0	0	0				
		Mild	5 (6.6%)	2 (4.9%)	7 (6.0%)	1.3611 [0.2556, 7.2466]	1.3459 [0.2661, 6.8075]	0.0168 [-0.0702, 0.1038]	0.5493
		Moderate	0	0	0		0.7167		0.9725
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 43 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value	
			n	%		n	%			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Endocrine disorders	Diabetes insipidus		1	(1.3%)		1	(2.4%)		2	(1.7%)				
		Mild	1	(1.3%)	1	(2.4%)	2	(1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465] 0.6496	-0.0114 [-0.0651, 0.0422]	0.9988		
		Moderate	0		0		0							
		Secondary adrenocortical insufficiency		1	(1.3%)	1	(2.4%)	2	(1.7%)					
	Mild		1	(1.3%)	1	(2.4%)	2	(1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465] 0.6496	-0.0114 [-0.0651, 0.0422]	0.9988		
	Moderate		0		0		0							
		Adrenal insufficiency		0		0		0						
	Mild		0		0		0							
	Moderate		0		0		0					0.9725		
		Hypothyroidism		0		0		0						
	Mild		0		0		0						0.9750	
	Moderate		0		0		0							
			Severe	0		0		0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 44 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations			6 (7.9%)	3 (7.3%)	9 (7.7%)				
		Mild	6 (7.9%)	3 (7.3%)	9 (7.7%)	1.0795 [0.2549, 4.5714]	1.0729 [0.2847, 4.0437] 0.9177	0.0054 [-0.0947, 0.1054]	0.9764
		Moderate	0	0	0				
		Severe	0	0	0				
	Insulin-like growth factor increased		2 (2.6%)	0	2 (1.7%)				
		Mild	2 (2.6%)	0	2 (1.7%)	1.7336 [0.1724, 17.4348]	1.6939 [0.1842, 15.5745] 0.2952	0.0266 [-0.0096, 0.0627]	0.9728
		Moderate	0	0	0				
		Severe	0	0	0				
	Alanine aminotransferase increased		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 45 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Safety Population			LonapegSomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Aspartate aminotransferase increased		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood cortisol decreased		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood iron decreased		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 46 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76) Genotropin (N=41) Total (N=117)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value	
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>					
Investigations	Blood iron increased		0	1 (2.4%)	1 (0.9%)					
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743	
		Moderate	0	0	0					
		Severe	0	0	0					
	Blood thyroid stimulating hormone increased			1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808	
		Moderate	0	0	0					
		Severe	0	0	0					
	Cortisol free urine decreased			1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808	
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 47 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Investigations	Thyroxine decreased		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	0	0	0				
	Transaminases increased	Severe	0	0	0				
			1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	White blood cell count decreased	Moderate	0	0	0				
		Severe	0	0	0				
			1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 48 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Investigations	Eosinophil count increased		0	0	0								
		Mild	0	0	0								0.9741
		Moderate	0	0	0								
		Severe	0	0	0								
Immune system disorders			6 (7.9%)	1 (2.4%)	7 (6.0%)								
		Mild	5 (6.6%)	1 (2.4%)	6 (5.1%)	2.8182 [0.3149, 25.2237]	2.6667 [0.3253, 21.8578]	0.0408 [-0.0317, 0.1134]					0.3447
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]					0.9808
		Severe	0	0	0								
	Seasonal allergy		4 (5.3%)	0	4 (3.4%)								
		Mild	4 (5.3%)	0	4 (3.4%)	5.1770 [0.2700, 99.2515]	4.8689 [0.2704, 87.6840]	0.0522 [0.0022, 0.1023]					0.9450
		Moderate	0	0	0								
		Severe	0	0	0								

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 49 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Immune system disorders	Hypersensitivity		1 (1.3%)	1 (2.4%)	2 (1.7%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9743
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
	Allergy to animal	Severe	0	0	0		0.1709 0.4652		
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9981
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood and lymphatic system disorders		6 (7.9%)	0	6 (5.1%)				
		Mild	4 (5.3%)	0	4 (3.4%)	2.7995 [0.3047, 25.7188]	2.6416 [0.3134, 22.2663]	0.0527 [0.0025, 0.1029]	0.9642

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 50 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Blood and lymphatic system disorders	Iron deficiency anaemia	Moderate	2 (2.6%)	0	2 (1.7%)	1.7336 [0.1724, 17.4348]	1.6939 [0.1842, 15.5745]	0.0266 [-0.0096, 0.0627]	0.9728
		Severe	0	0	0		0.2952		
	Neutropenia	Mild	2 (2.6%)	0	2 (1.7%)	1.7336 [0.1724, 17.4348]	1.6939 [0.1842, 15.5745]	0.0266 [-0.0096, 0.0627]	0.9728
		Moderate	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233]	0.0135 [-0.0124, 0.0395]	0.9808
	Lymphadenopathy	Severe	0	0	0		0.4533		
		Mild	2 (2.6%)	0	2 (1.7%)	2.7778 [0.1294, 59.6290]	2.7049 [0.1338, 54.6938]	0.0261 [-0.0097, 0.0620]	0.9728
	Lymphadenopathy	Moderate	0	0	0		0.2990		
		Severe	0	0	0				
		Mild	1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				0.9750

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 51 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>					
Blood and lymphatic system disorders	Lymphadenopathy	Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808				
		Severe	0	0	0								
	Anaemia	Mild	0	0	0				0.9988				
		Moderate	0	0	0								
		Severe	0	0	0								
Eye disorders	Mild	4 (5.3%)	2 (4.9%)	6 (5.1%)	1.0800 [0.1902, 6.1335]	1.0760 [0.2064, 5.6099]	0.0037 [-0.0794, 0.0868]	0.9685					
		4 (5.3%)	2 (4.9%)	6 (5.1%)		0.9311							
	Moderate	0	0	0									
		0	0	0									
	Strabismus	Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9988				
		1 (1.3%)	1 (2.4%)	2 (1.7%)		0.6496							
		Moderate	0	0	0								
Severe	0	0	0										

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 52 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Eye disorders	Conjunctivitis allergic		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye swelling		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypermetropia		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
Myopia		0	1 (2.4%)	1 (0.9%)					
	Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743	
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 53 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
			TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)				
Eye disorders	Astigmatism		0	0	0				
		Mild	0	0	0				0.9725
		Moderate	0	0	0				
	Eye haemorrhage	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				0.9725
		Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				
Ear and labyrinth disorders			4 (5.3%)	0	4 (3.4%)				
		Mild	4 (5.3%)	0	4 (3.4%)	2.7995 [0.3047, 25.7188]	2.6416 [0.3134, 22.2663] 0.1381	0.0527 [0.0025, 0.1029]	0.9743
		Moderate	0	0	0				
	Ear pain	Severe	0	0	0				
			4 (5.3%)	0	4 (3.4%)				
		Mild	4 (5.3%)	0	4 (3.4%)	2.7995 [0.3047, 25.7188]	2.6416 [0.3134, 22.2663] 0.1381	0.0527 [0.0025, 0.1029]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 54 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Psychiatric disorders			2 (2.6%)	1 (2.4%)	3 (2.6%)				
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5254 [0.0318, 8.6898]	0.5333 [0.0345, 8.2465]	-0.0114 [-0.0651, 0.0422]	0.9748
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	0.6496 1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Severe	0	0	0		0.4652		
	Affect lability		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336]	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
	Attention deficit/hyperactivity disorder		0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037]	-0.0245 [-0.0718, 0.0228]	0.9540
		Moderate	0	0	0		0.1709		
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 55 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Psychiatric disorders	Depressive symptom		1 (1.3%)	0	1 (0.9%)					
		Mild	0	0	0					
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808	
	Enuresis	Severe	0	0	0					
			0	0	0					
		Mild	0	0	0				0.9725	
		Moderate	0	0	0					
		Severe	0	0	0					
	Cardiac disorders			2 (2.6%)	0	2 (1.7%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808	
Moderate		1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808		
Severe		0	0	0						

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 56 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76) Genotropin (N=41) Total (N=117)			Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>				
Cardiac disorders	Sinoatrial block		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
	Sinus tachycardia		1 (1.3%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	Tachycardia		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 57 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Organ Preferred Term	Severity	Incidence			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
			TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			1 (1.3%)	1 (2.4%)	2 (1.7%)				
		Mild	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5520 [0.0347, 8.7756]	0.5520 [0.0358, 8.5079] 0.6657	-0.0110 [-0.0654, 0.0434]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
		Osteoma	1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.8387 [0.0678, 49.8983]	1.7647 [0.0792, 39.3233] 0.4533	0.0135 [-0.0124, 0.0395]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
		Skin papilloma	0	1 (2.4%)	1 (0.9%)				
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9426
	Moderate	0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 58 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Organ Preferred Term	Severity	Lonapegsomatropin vs. Genotropina <sup>a</sup>						
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	Subgroup Interaction p-value
Reproductive system and breast disorders			0	2 (4.9%)	2 (1.7%)				
		Mild	0	2 (4.9%)	2 (1.7%)	0.1727 [0.0171, 1.7396]	0.1882 [0.0205, 1.7305] 0.0560	-0.0485 [-0.1143, 0.0173]	0.9757
		Moderate	0	0	0				
		Severe	0	0	0				
		Penile adhesion		0	2 (4.9%)	2 (1.7%)			
		Mild	0	2 (4.9%)	2 (1.7%)	0.1727 [0.0171, 1.7396]	0.1882 [0.0205, 1.7305] 0.0560	-0.0485 [-0.1143, 0.0173]	0.9757
		Moderate	0	0	0				
		Severe	0	0	0				
		Genital discomfort		0	1 (2.4%)	1 (0.9%)			
		Mild	0	1 (2.4%)	1 (0.9%)	0.1717 [0.0063, 4.6830]	0.1961 [0.0088, 4.3693] 0.1824	-0.0240 [-0.0709, 0.0229]	0.9743
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 59 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	Safety Population			Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value	
			TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>		
Hepatobiliary disorders			0	1 (2.4%)	1 (0.9%)					
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743	
		Moderate	0	0	0					
		Severe	0	0	0					
		Hepatomegaly								
		Mild	0	1 (2.4%)	1 (0.9%)	0.1736 [0.0069, 4.3850]	0.1803 [0.0076, 4.3037] 0.1709	-0.0245 [-0.0718, 0.0228]	0.9743	
		Moderate	0	0	0					
		Severe	0	0	0					
	Metabolism and nutrition disorders			1 (1.3%)	0	1 (0.9%)				
			Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0					
		Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 60 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)	Genotropin n (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Metabolism and nutrition disorders	Polydipsia		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
		Severe	0	0	0				
Renal and urinary disorders			1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9981
		Moderate	0	0	0				
	Polyuria		1 (1.3%)	0	1 (0.9%)				
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
		Moderate	0	0	0				
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 61 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: < 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=76)			Genotropin n (N=41)			Total (N=117)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			Subgroup Interaction p-value
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Renal and urinary disorders	Pollakiuria		0	0	0								
		Mild	0	0	0							0.9725	
		Moderate	0	0	0								
		Severe	0	0	0								
Vascular disorders			1 (1.3%)	0	1 (0.9%)								
		Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]		0.9981			
		Moderate	0	0	0								
		Severe	0	0	0								
	Hypotension			1 (1.3%)	0	1 (0.9%)							
			Mild	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]		0.9981		
			Moderate	0	0	0							
			Severe	0	0	0							

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 62 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

		Peak stimulated GH concentration at baseline: >= 8 ng/mL						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Any adverse event			21 (72.4%)	9 (60.0%)	30 (68.2%)			
	Mild		13 (44.8%)	5 (33.3%)	18 (40.9%)	1.6299 [0.4442, 5.9812]	1.3478 [0.5912, 3.0729]	0.1157 [-0.1838, 0.4151]
	Moderate	8 (27.6%)	4 (26.7%)	12 (27.3%)	1.0494 [0.2596, 4.2423]	1.0360 [0.3715, 2.8896]	0.0096 [-0.2687, 0.2880]	
	Severe	0	0	0				
Infections and infestations			15 (51.7%)	9 (60.0%)	24 (54.5%)			
	Mild		12 (41.4%)	6 (40.0%)	18 (40.9%)	1.0723 [0.3012, 3.8181]	1.0422 [0.4907, 2.2132]	0.0169 [-0.2893, 0.3230]
	Moderate	3 (10.3%)	3 (20.0%)	6 (13.6%)	0.4624 [0.0811, 2.6355]	0.5181 [0.1187, 2.2608]	-0.0964 [-0.3273, 0.1345]	
	Severe	0	0	0				
	Nasopharyngitis		2 (6.9%)	3 (20.0%)	5 (11.4%)			
	Mild		2 (6.9%)	3 (20.0%)	5 (11.4%)	0.3005 [0.0443, 2.0381]	0.3494 [0.0659, 1.8516]	-0.1301 [-0.3529, 0.0926]
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 63 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Upper respiratory tract infection		4 (13.8%)	1 (6.7%)	5 (11.4%)			
		Mild	4 (13.8%)	0	4 (9.1%)	3.2127 [0.3395, 30.4023]	2.8086 [0.3603, 21.8944] 0.1349	0.1398 [0.0136, 0.2659]
		Moderate	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398] 0.1573	-0.0675 [-0.1944, 0.0594]
	Pharyngitis	Severe	0	0	0			
		Mild	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.4444 [0.0528, 3.7383]	0.5000 [0.0821, 3.0461] 0.4552	-0.0675 [-0.2585, 0.1236]
		Moderate	0	0	0			
	Pharyngitis streptococcal	Severe	0	0	0			
		Mild	0	4 (26.7%)	4 (9.1%)			
		Moderate	0	2 (13.3%)	2 (4.5%)	0.0829 [0.0036, 1.9157]	0.1048 [0.0055, 1.9964] 0.0418	-0.1349 [-0.3077, 0.0378]
		Severe	0	2 (13.3%)	2 (4.5%)	0.0829 [0.0036, 1.9157]	0.1048 [0.0055, 1.9964] 0.0418	-0.1349 [-0.3077, 0.0378]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 64 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Sinusitis		2 (6.9%)	1 (6.7%)	3 (6.8%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5357 [0.0341, 8.4088]	0.5357 [0.0360, 7.9707]	-0.0313 [-0.1786, 0.1159]
		Moderate	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928]	0.0361 [-0.0318, 0.1041]
	Bronchitis	Severe	0	0	0		0.6452 0.4561	
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.0337 [-0.0320, 0.0995]
		Moderate	0	1 (6.7%)	1 (2.3%)	0.1579 [0.0053, 4.6909]	0.2000 [0.0096, 4.1659]	-0.0651 [-0.1900, 0.0599]
	Enterobiasis	Severe	0	0	0		0.4795 0.1797	
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.4737 [0.0265, 8.4640]	0.5000 [0.0348, 7.1900]	-0.0337 [-0.1752, 0.1077]
		Moderate	0	0	0		0.6109	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 65 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Respiratory tract infection		2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	3.6667 [0.1451, 92.6525]	3.0000 [0.1713, 52.5268] 0.2726	0.0723 [-0.0218, 0.1664]
		Moderate	0	0	0			
		Severe	0	0	0			
	Respiratory tract infection viral		1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5185 [0.0318, 8.4442]	0.5185 [0.0301, 8.9280] 0.6452	-0.0313 [-0.1754, 0.1128]
		Moderate	0	0	0			
		Severe	0	0	0			
	Varicella		2 (6.9%)	0	2 (4.5%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 66 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL						Lonapegsomatropin vs. Genotropina <sup>a</sup>		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropi n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Conjunctivitis		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
	Ear infection	Severe	0	0	0			
			1 (3.4%)	0	1 (2.3%)			
		Mild	0	0	0			
	Molluscum contagiosum	Moderate	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Severe	0	0	0			
			1 (3.4%)	0	1 (2.3%)			
	Rhinitis	Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
		1 (3.4%)	0	1 (2.3%)				
	Mild	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 67 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL						Lonapegsomatropin vs. Genotropina <sup>a</sup>		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropi n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Tinea pedis		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
	Tonsillitis	Severe	0	0	0			
		Mild	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]
		Moderate	0	0	0			
	Tooth abscess	Severe	0	0	0			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
	Urinary tract infection	Severe	0	0	0			
		Mild	0	1 (6.7%)	1 (2.3%)			
		Moderate	0	1 (6.7%)	1 (2.3%)	0.1579 [0.0053, 4.6909]	0.2000 [0.0096, 4.1659] 0.1797	-0.0651 [-0.1900, 0.0599]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 68 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Appendicitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Atypical pneumonia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Croup infectious		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cystitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 69 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Infections and infestations	Eczema and infected		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Enteritis infectious			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastroenteritis			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastroenteritis viral			0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Helminthic infection			0	0	0			
		Mild	0	0	0				
Moderate		0	0	0					
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 70 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Hordeolum		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Infected bite	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Influenza	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Laryngitis viral	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Otitis externa	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 71 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Infections and infestations	Otitis media acute		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngotonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pneumonia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pulpitis dental		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rotavirus infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 72 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropi n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR	RD
							[95 %-CI] <sup>b</sup>	p-value <sup>c</sup>
Infections and infestations	Viral infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Viral upper respiratory tract infection	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Vulvitis	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Respiratory, thoracic and mediastinal disorders	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			8 (27.6%)	4 (26.7%)	12 (27.3%)			
	Mild	7 (24.1%)	2 (13.3%)	9 (20.5%)	2.0714 [0.3725, 11.5181]	1.8182 [0.4254, 7.7712] 0.4093	0.1084 [-0.1238, 0.3407]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 73 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL						Lonapegsomatropin vs. Genotropina <sup>a</sup>			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	RR			
						OR [95 %-CI] <sup>b</sup>	[95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2679 [0.0250, 2.8664]	0.2679 [0.0260, 2.7581]	-0.0988 [-0.2896, 0.0920]	
		Severe	0	0	0		0.2291		
		Mild	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.4444 [0.0528, 3.7383]	0.5000 [0.0821, 3.0461]	-0.0675 [-0.2585, 0.1236]	
	Asthma	Moderate	Moderate	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398]	-0.0675 [-0.1944, 0.0594]
			Severe	0	0	0		0.1573	
		Mild	Mild	2 (6.9%)	1 (6.7%)	3 (6.8%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.0337 [-0.0320, 0.0995]
			Moderate	1 (3.4%)	0	1 (2.3%)	0.4795	0.5357	-0.0313
		Severe	Moderate	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5357 [0.0341, 8.4088]	0.5357 [0.0360, 7.9707]	-0.0313 [-0.1786, 0.1159]
			Severe	0	0	0		0.6452	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 74 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5185 [0.0318, 8.4442]	0.5185 [0.0301, 8.9280] 0.6452	-0.0313 [-0.1754, 0.1128]
		Moderate	0	0	0			
	Sinus congestion	Severe	0	0	0			
			2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265] 0.3043	0.0699 [-0.0229, 0.1627]
	Epistaxis	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]
	Respiratory disorder	Moderate	0	0	0			
		Severe	0	0	0			
			0	1 (6.7%)	1 (2.3%)			
	Mild	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 75 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	Moderate	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398]	-0.0675 [-0.1944, 0.0594]
		Severe	0	0	0		0.1573	
	Allergic cough	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Dyspnoea exertional	0	0	0			
	Laryngospasm	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal congestion	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 76 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropi n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR	RD
							[95 %-CI] <sup>b</sup>	p-value <sup>c</sup>
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Rhinorrhoea	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Sleep apnoea syndrome	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Wheezing	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastrointestinal disorders		7 (24.1%)	3 (20.0%)	10 (22.7%)			
		Mild	7 (24.1%)	2 (13.3%)	9 (20.5%)	2.0045 [0.3759, 10.6898]	1.8036 [0.4230, 7.6906]	0.1084 [-0.1295, 0.3464]

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 77 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Diarrhoea	Moderate	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398] 0.1573	-0.0675 [-0.1944, 0.0594]
		Severe	0	0	0			
		Mild	2 (6.9%)	1 (6.7%)	3 (6.8%)	1.0376 [0.0898, 11.9848]	1.0357 [0.1026, 10.4584] 0.9766	0.0024 [-0.1565, 0.1613]
	Constipation	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265] 0.3043	0.0699 [-0.0229, 0.1627]
	Nausea	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398] 0.1573	-0.0675 [-0.1944, 0.0594]
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 78 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Toothache		1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.4737 [0.0265, 8.4640]	0.5000 [0.0348, 7.1900] 0.6109	-0.0337 [-0.1752, 0.1077]
		Moderate	0	0	0			
	Vomiting	Severe	0	0	0			
			1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5357 [0.0341, 8.4088]	0.5357 [0.0360, 7.9707] 0.6452	-0.0313 [-0.1786, 0.1159]
	Abdominal discomfort	Moderate	0	0	0			
		Severe	0	0	0			
			1 (3.4%)	0	1 (2.3%)			
	Abdominal pain upper	Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
		1 (3.4%)	0	1 (2.3%)				
	Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]	
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 79 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Dyspepsia		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]
		Moderate	0	0	0			
	Abdominal pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Aphthous ulcer	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Gastric disorder	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 80 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Gastrointestinal disorders	Gastrointestinal motility disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Lip swelling	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
			6 (20.7%)	2 (13.3%)	8 (18.2%)			
Nervous system disorders	Headache	Mild	5 (17.2%)	1 (6.7%)	6 (13.6%)	3.0000 [0.3006, 29.9400]	2.5000 [0.3355, 18.6278] 0.3411	0.1012 [-0.0795, 0.2819]
		Moderate	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.4737 [0.0265, 8.4640]	0.5000 [0.0348, 7.1900] 0.6109	-0.0337 [-0.1752, 0.1077]
		Severe	0	0	0			
	Mild	5 (17.2%)	1 (6.7%)	6 (13.6%)				
		4 (13.8%)	0	4 (9.1%)	5.7273 [0.2788, 117.6479]	4.7143 [0.2784, 79.8226] 0.1353	0.1349 [0.0103, 0.2596]	

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 81 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Nervous system disorders	Headache	Moderate	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.4737 [0.0265, 8.4640]	0.5000 [0.0348, 7.1900]	-0.0337 [-0.1752, 0.1077]
		Severe	0	0	0	0.6109		
	Dizziness	Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0	0.4795		
	Post-traumatic headache	Severe	0	0	0			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398]	-0.0675 [-0.1944, 0.0594]
	Migraine	Moderate	0	0	0	0.1573		
		Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Tremor	Severe	0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 82 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL						Lonapegsomatropin vs. Genotropina <sup>a</sup>		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications			6 (20.7%)	1 (6.7%)	7 (15.9%)			
		Mild	4 (13.8%)	1 (6.7%)	5 (11.4%)	2.2185 [0.2232, 22.0536]	2.0357 [0.2545, 16.2865]	0.0699 [-0.1077, 0.2474]
		Moderate	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265]	0.0699 [-0.0229, 0.1627]
		Severe	0	0	0		0.4956 0.3043	
		Animal bite						
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0		0.4795	
		Severe	0	0	0			
		Arthropod bite						
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0		0.4795	
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropi n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Burns first degree		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398] 0.1573	-0.0675 [-0.1944, 0.0594]
		Moderate	0	0	0			
	Burns second degree	Severe	0	0	0			
			1 (3.4%)	0	1 (2.3%)			
		Mild	0	0	0			
	Contusion	Moderate	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]
		Severe	0	0	0			
		Mild	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]
	Fall	Moderate	0	0	0			
		Severe	0	0	0			
		Mild	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]
			Moderate	0	0	0		
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 84 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Muscle strain		1 (3.4%)	0	1 (2.3%)			
		Mild	0	0	0			
		Moderate	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
	Wrist fracture	Severe	0	0	0			
			1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
	Ankle fracture	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Concussion	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 85 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Face injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Head injury	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Laceration	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Ligament sprain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Meniscus injury	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 86 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Injury, poisoning and procedural complications	Post-traumatic pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Radius fracture	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Thermal burn	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Upper limb fracture	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 87 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Endocrine disorders			3 (10.3%)	2 (13.3%)	5 (11.4%)				
		Mild	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2679 [0.0250, 2.8664]	0.2679 [0.0260, 2.7581] 0.2291	-0.0988 [-0.2896, 0.0920]	
		Moderate	2 (6.9%)	0	2 (4.5%)	2.8378 [0.1241, 64.8722]	2.6190 [0.1374, 49.9110] 0.3088	0.0675 [-0.0239, 0.1589]	
		Severe	0	0	0				
		Secondary hypothyroidism		2 (6.9%)	1 (6.7%)	3 (6.8%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5357 [0.0341, 8.4088]	0.5357 [0.0360, 7.9707] 0.6452	-0.0313 [-0.1786, 0.1159]	
		Moderate	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]	
		Severe	0	0	0				
		Adrenal insufficiency		1 (3.4%)	0	1 (2.3%)			
		Mild	0	0	0				
		Moderate	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]	
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 88 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Endocrine disorders	Hypothyroidism		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398] 0.1573	-0.0675 [-0.1944, 0.0594]
		Moderate	0	0	0			
	Diabetes insipidus	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Secondary adrenocortical insufficiency	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Mild	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions			2 (6.9%)	3 (20.0%)	5 (11.4%)			
		Mild	1 (3.4%)	3 (20.0%)	4 (9.1%)	0.1228 [0.0109, 1.3858]	0.1667 [0.0198, 1.4054] 0.0619	-0.1687 [-0.3791, 0.0418]
		Moderate	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Severe	0	0	0			
		Pyrexia						
		Mild	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2105 [0.0166, 2.6657]	0.2500 [0.0256, 2.4375] 0.2043	-0.1012 [-0.2837, 0.0813]
		Moderate	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Severe	0	0	0			
		Injection site swelling						
		Mild	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398] 0.1573	-0.0675 [-0.1944, 0.0594]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and administration site conditions	Face oedema		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Fatigue	Severe	0	0	0			
			0	0	0			
		Mild	0	0	0			
	Gait disturbance	Moderate	0	0	0			
		Severe	0	0	0			
			0	0	0			
	Influenza like illness	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 91 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
General disorders and site administration site conditions	Injection site urticaria	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site urticaria	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Medical device discomfort	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vaccination site pain	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 92 of 112



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>					
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders			2 (6.9%)	2 (13.3%)	4 (9.1%)			
		Mild	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.4862 [0.0604, 3.9141]	0.5273 [0.0835, 3.3275] 0.5027	-0.0627 [-0.2565, 0.1312]
		Moderate	0	0	0			
		Severe	0	0	0			
		Arthralgia						
		Mild	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265] 0.3043	0.0699 [-0.0229, 0.1627]
		Moderate	0	0	0			
		Severe	0	0	0			
		Pain in extremity						
		Mild	0	2 (13.3%)	2 (4.5%)	0.1561 [0.0147, 1.6569]	0.1872 [0.0213, 1.6474] 0.0514	-0.1325 [-0.3042, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 93 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Musculoskeletal and connective tissue disorders	Arthritis reactive		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Back pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Musculoskeletal pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck mass	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neck pain	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 94 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: $\geq 8$ ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Pain in jaw		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Synovial cyst		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Blood and lymphatic system disorders	Anaemia		1 (3.4%)	2 (13.3%)	3 (6.8%)			
			Mild	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2679 [0.0250, 2.8664]	0.2679 [0.0260, 2.7581] 0.2291	-0.0988 [-0.2896, 0.0920]
			Moderate	0	0	0			
Anaemia			1 (3.4%)	1 (6.7%)	2 (4.5%)				
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5357 [0.0341, 8.4088]	0.5357 [0.0360, 7.9707] 0.6452	-0.0313 [-0.1786, 0.1159]	
		Moderate	0	0	0				
			0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 95 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Blood and lymphatic system disorders	Lymphadenopathy		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398] 0.1573	-0.0675 [-0.1944, 0.0594]
		Moderate	0	0	0			
		Severe	0	0	0			
	Iron deficiency anaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Neutropenia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Eye disorders		2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	2.8378 [0.1241, 64.8722]	2.6190 [0.1374, 49.9110] 0.3088	0.0675 [-0.0239, 0.1589]
		Moderate	0	0	0			
Severe		0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 96 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Eye disorders	Astigmatism		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye haemorrhage		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis allergic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Eye swelling		0	0	0				
	Mild	0	0	0				
	Moderate	0	0	0				
	Severe	0	0	0				
Hypermetropia		0	0	0				
	Mild	0	0	0				
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 97 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)			Genotropin n (N=15)			Total (N=44)			Lonapegsomatropin vs. Genotropin <sup>a</sup>		
			OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup>	p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>								
Eye disorders	Myopia	Mild	0	0	0									
		Moderate	0	0	0									
		Severe	0	0	0									
	Strabismus	Mild	0	0	0									
		Moderate	0	0	0									
		Severe	0	0	0									
	Immune system disorders			1 (3.4%)	1 (6.7%)	2 (4.5%)								
			Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.4737 [0.0265, 8.4640]	0.5000 [0.0348, 7.1900]	0.6109	-0.0337 [-0.1752, 0.1077]				
			Moderate	0	0	0								
Allergy to animal		Severe	0	0	0									
		Mild	1 (3.4%)	0	1 (2.3%)									
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.4795	0.0337 [-0.0320, 0.0995]					
		Moderate	0	0	0									
		Severe	0	0	0									

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 98 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL			Lonapegsomatropin vs. Genotropina <sup>a</sup>						
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropi n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Immune system disorders	Seasonal allergy		0	1 (6.7%)	1 (2.3%)				
		Mild	0	1 (6.7%)	1 (2.3%)	0.1545 [0.0057, 4.1537]	0.1746 [0.0077, 3.9398] 0.1573	-0.0675 [-0.1944, 0.0594]	
		Moderate	0	0	0				
	Hypersensitivity	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				
	Investigations			2 (6.9%)	0	2 (4.5%)			
			Mild	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265] 0.3043	0.0699 [-0.0229, 0.1627]
			Moderate	0	0	0			
Eosinophil count increased		Severe	0	0	0				
			2 (6.9%)	0	2 (4.5%)				
		Mild	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265] 0.3043	0.0699 [-0.0229, 0.1627]	
		Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Alanine aminotransferase increased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Aspartate aminotransferase increased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood cortisol decreased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood iron decreased	Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Blood iron increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Blood thyroid stimulating hormone increased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Cortisol free urine decreased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Insulin-like growth factor increased	Severe	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
			Severe	0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 101 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Investigations	Thyroxine decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Transaminases increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	White blood cell count decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 102 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	2.8378 [0.1241, 64.8722]	2.6190 [0.1374, 49.9110] 0.3088	0.0675 [-0.0239, 0.1589]
		Moderate	0	0	0			
		Severe	0	0	0			
		Skin papilloma	2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	2.8378 [0.1241, 64.8722]	2.6190 [0.1374, 49.9110] 0.3088	0.0675 [-0.0239, 0.1589]
		Moderate	0	0	0			
		Severe	0	0	0			
		Osteoma	0	0	0			
		Mild	0	0	0			
	Moderate	0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Psychiatric disorders			2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	3.6667 [0.1451, 92.6525]	3.0000 [0.1713, 52.5268] 0.2726	0.0723 [-0.0218, 0.1664]
		Moderate	0	0	0			
		Severe	0	0	0			
		Attention deficit/hyperactivity disorder	1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]
		Moderate	0	0	0			
		Severe	0	0	0			
		Enuresis	1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.9412 [0.0664, 56.7602]	1.8000 [0.0864, 37.4928] 0.4561	0.0361 [-0.0318, 0.1041]
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 104 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Psychiatric disorders	Affect lability		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
	Depressive symptom	Severe	0	0	0				
			0	0	0				
		Mild	0	0	0				
	Skin and subcutaneous tissue disorders	Rash	Moderate	0	0	0			
			Severe	0	0	0			
				2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265] 0.3043	0.0699 [-0.0229, 0.1627]
		Mild	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265] 0.3043	0.0699 [-0.0229, 0.1627]	
			2 (6.9%)	0	2 (4.5%)				
		Moderate	0	0	0				
		Severe	0	0	0				
			0	0	0				
			0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Skin and subcutaneous tissue disorders	Cafe au lait spots		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis allergic			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Dermatitis contact			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Eczema			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			
	Keratosis pilaris			0	0	0			
		Mild		0	0	0			
		Moderate		0	0	0			
		Severe		0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 106 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Skin and subcutaneous tissue disorders	Petechiae		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pityriasis alba		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rash erythematous		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Rash pruritic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria		0	0	0			
		Mild	0	0	0			
Moderate		0	0	0				
	Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 107 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL						Lonapegsomatropin vs. Genotropina <sup>a</sup>			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Renal and urinary disorders			1 (3.4%)	0	1 (2.3%)				
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Pollakiuria		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]	
		Moderate	0	0	0				
		Severe	0	0	0				
		Polyuria		0	0	0			
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
Vascular disorders			1 (3.4%)	0	1 (2.3%)				
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]	
		Moderate	0	0	0				
		Severe	0	0	0				

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019



Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>	
Vascular disorders	Hypotension		1 (3.4%)	0	1 (2.3%)				
		Mild	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581] 0.4795	0.0337 [-0.0320, 0.0995]	
		Moderate	0	0	0				
		Severe	0	0	0				
Cardiac disorders			0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				
		Sinoatrial block		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
		Sinus tachycardia		0	0	0			
			Mild	0	0	0			
			Moderate	0	0	0			
	Severe	0	0	0					

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 109 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Cardiac disorders	Tachycardia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Ear and labyrinth disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Ear pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Hepatobiliary disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
	Hepatomegaly		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 110 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropin <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Metabolism and nutrition disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Polydipsia	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
				0	0	0		
Reproductive system and breast disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
		Genital discomfort	0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
				0	0	0		

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 111 of 112

Table 1.34 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated GH concentration at baseline Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$  ng/mL

System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Genotropin n (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>		
						OR [95 %-CI] <sup>b</sup>	RR [95 %-CI] <sup>b</sup> p-value <sup>c</sup>	RD [95 %-CI] <sup>b</sup>
Reproductive system and breast disorders	Penile and breast disorders		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			

Each subject will be counted only once within each preferred term. If a subject experiences more than one TEAE within a preferred term only the TEAE with the maximum severity will be included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-teae-maxsev-sub.sas  
Data Extracted: 03May2019

v9.4 23FEB2023:22:43 Page 112 of 112

Table 1.43 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age Safety Population

Age: < 6 years

Symptom	Severity	TransCon hGH (N=25)	Genotropin (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771]	0.0800 [-0.0263, 0.1863]	0.9821
	MILD	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771]	0.0800 [-0.0263, 0.1863]	0.9735
	MODERATE	0	0	0		0.2835		0.9816
	SEVERE	0	0	0				
Bruising	ANY	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9549
	MILD	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9549
	MODERATE	0	0	0		0.4543		
	SEVERE	0	0	0				
Swelling	ANY	0	0	0				0.9800
	MILD	0	0	0				0.9800
	MODERATE	0	0	0				
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 1 of 4

Table 1.43 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age Safety Population

Age: < 6 years

Symptom	Severity	TransCon hGH (N=25)	Genotropin (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9996
	MILD	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631] 0.4543	0.0400 [-0.0368, 0.1168]	0.9996
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		4 (16.0%)	0	4 (10.3%)	6.0698 [0.3032, 121.5122]	5.1923 [0.2998, 89.9247]	0.1600 [0.0163, 0.3037]	0.9787
					0.1189			

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

Table 1.43 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age Safety Population

Age: >=6 years

Symptom	Severity	TransCon hGH (N=80)	Genotropin (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	22 (27.5%)	2 (4.8%)	24 (19.7%)	7.5862 [1.6884, 34.0853]	5.7750 [1.4262, 23.3842] 0.0028	0.2274 [0.1102, 0.3445]	
	MILD	21 (26.3%)	2 (4.8%)	23 (18.9%)	7.1186 [1.5806, 32.0611]	5.5125 [1.3573, 22.3876] 0.0041	0.2149 [0.0989, 0.3308]	
	MODERATE	1 (1.3%)	0	1 (0.8%)	1.6038 [0.0639, 40.2280]	1.5926 [0.0663, 38.2649] 0.4687	0.0125 [-0.0118, 0.0368]	
	SEVERE	0	0	0				
Bruising	ANY	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]	
	MILD	0	1 (2.4%)	1 (0.8%)	0.1718 [0.0068, 4.3114]	0.1770 [0.0074, 4.2517] 0.1675	-0.0238 [-0.0699, 0.0223]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	6 (7.5%)	0	6 (4.9%)	7.4161 [0.4076, 134.9177]	6.9012 [0.3982, 119.6139] 0.0699	0.0750 [0.0173, 0.1327]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 3 of 4

Table 1.43 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by age Safety Population

Age: >=6 years

Symptom	Severity	TransCon hGH (N=80)	Genotropin (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Swelling	MILD	6 (7.5%)	0	6 (4.9%)	7.4161 [0.4076, 134.9177]	6.9012 [0.3982, 119.6139] 0.0699	0.0750 [0.0173, 0.1327]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	4 (5.0%)	0	4 (3.3%)	5.0000 [0.2628, 95.1203]	4.7778 [0.2634, 86.6796] 0.1423	0.0500 [0.0022, 0.0978]	
	MILD	4 (5.0%)	0	4 (3.3%)	5.0000 [0.2628, 95.1203]	4.7778 [0.2634, 86.6796] 0.1423	0.0500 [0.0022, 0.0978]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		26 (32.5%)	3 (7.1%)	29 (23.8%)	6.2593 [1.7683, 22.1565]	4.5500 [1.4621, 14.1591]	0.2536 [0.1247, 0.3824]	
						0.0019		

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 4 of 4



Table 1.44 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender  
Safety Population

Male

Symptom	Severity	TransCon hGH (N=86)	Genotropin (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	18 (20.9%)	2 (4.3%)	20 (15.2%)	5.8799 [1.2753, 27.1096]	4.6036 [1.1353, 18.6670] 0.0129	0.1598 [0.0571, 0.2625]	0.9729
	MILD	17 (19.8%)	2 (4.3%)	19 (14.4%)	5.4436 [1.1771, 25.1734]	4.3498 [1.0680, 17.7166] 0.0184	0.1485 [0.0472, 0.2498]	0.9731
	MODERATE	1 (1.2%)	0	1 (0.8%)	1.5581 [0.0618, 39.2992]	1.5455 [0.0647, 36.9317] 0.4761	0.0113 [-0.0111, 0.0336]	0.9762
	SEVERE	0	0	0				
Bruising	ANY	0	0	0				0.9987
	MILD	0	0	0				0.9987
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	4 (4.7%)	0	4 (3.0%)	4.9024 [0.2561, 93.8438]	4.6364 [0.2571, 83.6154] 0.1477	0.0450 [0.0011, 0.0890]	0.9984
	MILD	4 (4.7%)	0	4 (3.0%)	4.9024 [0.2561, 93.8438]	4.6364 [0.2571, 83.6154] 0.1477	0.0450 [0.0011, 0.0890]	0.9984
	MODERATE	0	0	0				
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 1 of 4

Table 1.44 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender  
Safety Population

Male

Symptom	Severity	TransCon hGH (N=86)	Genotropin (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728]	0.0240 [-0.0084, 0.0564]	0.9963
	MILD	2 (2.3%)	0	2 (1.5%)	1.7516 [0.1759, 17.4418]	1.7202 [0.1853, 15.9728]	0.0240 [-0.0084, 0.0564]	0.9963
	MODERATE	0	0	0		0.2888		
	SEVERE	0	0	0		0.2888		
Overall number of abnormal injection-site reactions		20 (23.3%)	2 (4.3%)	22 (16.7%)	6.7334 [1.4720, 30.8002]	5.1457 [1.2782, 20.7149]	0.1838 [0.0780, 0.2897]	0.7692
								0.0063

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

Table 1.44 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender  
Safety Population

Female

Symptom	Severity	TransCon hGH (N=19)	Genotropin (N=10)	Total (N=29)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	6 (31.6%)	0	6 (20.7%)	4.4169 [0.4216, 46.2763]	2.8394 [0.4014, 20.0842] 0.0507	0.3230 [0.1088, 0.5371]	
	MILD	6 (31.6%)	0	6 (20.7%)	4.4169 [0.4216, 46.2763]	2.8394 [0.4014, 20.0842] 0.0507	0.3230 [0.1088, 0.5371]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Bruising	ANY	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.3200 [0.0117, 8.7358]	0.3200 [0.0098, 10.4012] 0.4986	-0.0661 [-0.2712, 0.1389]	
	MILD	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.3200 [0.0117, 8.7358]	0.3200 [0.0098, 10.4012] 0.4986	-0.0661 [-0.2712, 0.1389]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	2 (10.5%)	0	2 (6.9%)	3.5185 [0.1511, 81.9250]	3.1250 [0.1666, 58.6274] 0.2627	0.1167 [-0.0302, 0.2637]	
	MILD	2 (10.5%)	0	2 (6.9%)	3.5185 [0.1511, 81.9250]	3.1250 [0.1666, 58.6274] 0.2627	0.1167 [-0.0302, 0.2637]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 3 of 4

Table 1.44 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by gender  
Safety Population

Female

Symptom	Severity	TransCon hGH (N=19)	Genotropin (N=10)	Total (N=29)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	3 (15.8%)	0	3 (10.3%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826]	0.1751 [0.0016, 0.3486]	
	MILD	3 (15.8%)	0	3 (10.3%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826]	0.1751 [0.0016, 0.3486]	
	MODERATE	0	0	0		0.1603		
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		10 (52.6%)	1 (10.0%)	11 (37.9%)	10.5143 [1.0571, 104.5788]	5.4400 [0.7766, 38.1049]	0.4319 [0.1393, 0.7245]	
						0.0290		

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

Table 1.45 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 Safety Population

Baseline GH-stimulation strata: <=5ng/mL

Symptom	Severity	TransCon hGH (N=37)	Genotropin (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	11 (29.7%)	2 (9.5%)	13 (22.4%)	4.6316 [0.8923, 24.0415]	3.3000 [0.8230, 13.2318]	0.2154 [0.0256, 0.4051]	0.9673
	MILD	10 (27.0%)	2 (9.5%)	12 (20.7%)	4.0000 [0.7648, 20.9198]	3.0000 [0.7389, 12.1804]	0.1873 [0.0002, 0.3744]	0.9674
	MODERATE	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9718
	SEVERE	0	0	0				
Bruising	ANY	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.4800 [0.0253, 9.1006]	0.4800 [0.0235, 9.8096]	-0.0243 [-0.1281, 0.0794]	0.9990
	MILD	1 (2.7%)	1 (4.8%)	2 (3.4%)	0.4800 [0.0253, 9.1006]	0.4800 [0.0235, 9.8096]	-0.0243 [-0.1281, 0.0794]	0.9990
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	4 (10.8%)	0	4 (6.9%)	6.2830 [0.3187, 123.8813]	5.5161 [0.3142, 96.8409]	0.1124 [0.0105, 0.2142]	0.9969

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 1 of 4

Table 1.45 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 Safety Population

Baseline GH-stimulation strata: <=5ng/mL

Symptom	Severity	TransCon hGH (N=37)	Genotropin (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Swelling	MILD	4 (10.8%)	0	4 (6.9%)	6.2830 [0.3187, 123.8813]	5.5161 [0.3142, 96.8409]	0.1124 [0.0105, 0.2142]	0.9969
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9983
	MILD	1 (2.7%)	0	1 (1.7%)	1.8814 [0.0727, 48.6647]	1.8387 [0.0789, 42.8762]	0.0281 [-0.0253, 0.0815]	0.9983
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		13 (35.1%)	3 (14.3%)	16 (27.6%)	3.6000 [0.8623, 15.0295]	2.5600 [0.8295, 7.9010]	0.2191 [0.0087, 0.4295]	0.9756
								0.0739

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 2 of 4

Table 1.45 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 Safety Population

Baseline GH-stimulation strata: >5ng/mL

Symptom	Severity	TransCon hGH (N=68)	Genotropin (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	13 (19.1%)	0	13 (12.6%)	7.4804 [0.9004, 62.1461]	6.1800 [0.8141, 46.9145] 0.0066	0.1877 [0.0945, 0.2810]	
	MILD	13 (19.1%)	0	13 (12.6%)	7.4804 [0.9004, 62.1461]	6.1800 [0.8141, 46.9145] 0.0066	0.1877 [0.0945, 0.2810]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Bruising	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515] 0.3239	0.0281 [-0.0113, 0.0676]	
	MILD	2 (2.9%)	0	2 (1.9%)	2.5258 [0.1167, 54.6816]	2.4510 [0.1222, 49.1515] 0.3239	0.0281 [-0.0113, 0.0676]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 3 of 4

Table 1.45 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 Safety Population

Baseline GH-stimulation strata: >5ng/mL

Symptom	Severity	TransCon hGH (N=68)	Genotropin (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	4 (5.9%)	0	4 (3.9%)	2.7414 [0.2987, 25.1590]	2.5988 [0.3079, 21.9332] 0.1482	0.0587 [0.0027, 0.1147]	
	MILD	4 (5.9%)	0	4 (3.9%)	2.7414 [0.2987, 25.1590]	2.5988 [0.3079, 21.9332] 0.1482	0.0587 [0.0027, 0.1147]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		17 (25.0%)	0	17 (16.5%)	10.4999 [1.2968, 85.0138]	8.0855 [1.0971, 59.5907]	0.2464 [0.1435, 0.3494]	0.0014

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019



Table 1.46 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 Safety Population

Isolated idiopathic

Symptom	Severity	TransCon hGH (N=68)	Genotropin (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	11 (16.2%)	2 (5.4%)	13 (12.4%)	3.3603 [0.6898, 16.3703]	2.8883 [0.6891, 12.1057] 0.1190	0.1038 [-0.0085, 0.2162]	0.9988
	MILD	10 (14.7%)	2 (5.4%)	12 (11.4%)	2.9857 [0.6075, 14.6732]	2.6283 [0.6194, 11.1521] 0.1650	0.0895 [-0.0205, 0.1995]	0.9988
	MODERATE	1 (1.5%)	0	1 (1.0%)	1.6061 [0.0632, 40.8119]	1.5882 [0.0670, 37.6772] 0.4708	0.0143 [-0.0140, 0.0425]	0.9997
	SEVERE	0	0	0				
Bruising	ANY	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5766 [0.0377, 8.8058]	0.5766 [0.0402, 8.2631] 0.6814	-0.0116 [-0.0727, 0.0494]	1.0000
	MILD	1 (1.5%)	1 (2.7%)	2 (1.9%)	0.5766 [0.0377, 8.8058]	0.5766 [0.0402, 8.2631] 0.6814	-0.0116 [-0.0727, 0.0494]	1.0000
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	2 (2.9%)	0	2 (1.9%)	2.7320 [0.1264, 59.0317]	2.6471 [0.1317, 53.1845] 0.3046	0.0286 [-0.0111, 0.0683]	1.0000

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

Table 1.46 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 Safety Population

Isolated idiopathic

Symptom	Severity	TransCon hGH (N=68)	Genotropin (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Swelling	MILD	2 (2.9%)	0	2 (1.9%)	2.7320 [0.1264, 59.0317]	2.6471 [0.1317, 53.1845] 0.3046	0.0286 [-0.0111, 0.0683]	1.0000
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	4 (5.9%)	0	4 (3.8%)	2.8618 [0.3121, 26.2432]	2.7068 [0.3205, 22.8620] 0.1368	0.0587 [0.0028, 0.1147]	0.9996
	MILD	4 (5.9%)	0	4 (3.8%)	2.8618 [0.3121, 26.2432]	2.7068 [0.3205, 22.8620] 0.1368	0.0587 [0.0028, 0.1147]	0.9996
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		16 (23.5%)	3 (8.1%)	19 (18.1%)	3.4728 [0.9282, 12.9941]	2.8299 [0.8962, 8.9362] 0.0548	0.1509 [0.0180, 0.2839]	0.9994

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 2 of 6

Table 1.46 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 Safety Population

Isolated organic (determined by abnormal MRI)

Symptom	Severity	TransCon hGH (N=19)	Genotropin (N=9)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	8 (42.1%)	0	8 (28.6%)	16.7647 [0.8276, 339.6217]	9.3750 [0.5984, 146.8731] 0.0171	0.4667 [0.2142, 0.7191]	
	MILD	8 (42.1%)	0	8 (28.6%)	16.7647 [0.8276, 339.6217]	9.3750 [0.5984, 146.8731] 0.0171	0.4667 [0.2142, 0.7191]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Bruising	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
	MILD	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 3 of 6

Table 1.46 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 Safety Population

Isolated organic (determined by abnormal MRI)

Symptom	Severity	TransCon hGH (N=19)	Genotropin (N=9)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		8 (42.1%)	0	8 (28.6%)	16.7647 [0.8276, 339.6217]	9.3750 [0.5984, 146.8731]	0.4667 [0.2142, 0.7191]	
						0.0171		

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

Table 1.46 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 Safety Population

Multiple pituitary hormone deficiencies

Symptom	Severity	TransCon hGH (N=18)	Genotropin (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	5 (27.8%)	0	5 (17.9%)	7.8571 [0.3747, 164.7372]	5.5000 [0.3454, 87.5855]	0.2536 [0.0447, 0.4625]	
	MILD	5 (27.8%)	0	5 (17.9%)	7.8571 [0.3747, 164.7372]	5.5000 [0.3454, 87.5855]	0.2536 [0.0447, 0.4625]	
	MODERATE	0	0	0		0.0896		
	SEVERE	0	0	0				
Bruising	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	3 (16.7%)	0	3 (10.7%)	4.2000 [0.1895, 93.0809]	3.5000 [0.2047, 59.8483]	0.1522 [-0.0187, 0.3230]	
	MILD	3 (16.7%)	0	3 (10.7%)	4.2000 [0.1895, 93.0809]	3.5000 [0.2047, 59.8483]	0.1522 [-0.0187, 0.3230]	
	MODERATE	0	0	0		0.2135		
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 5 of 6

Table 1.46 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 Safety Population

Multiple pituitary hormone deficiencies

Symptom	Severity	TransCon hGH (N=18)	Genotropin (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]	
	MILD	1 (5.6%)	0	1 (3.6%)	1.5517 [0.0561, 42.9123]	1.5000 [0.0685, 32.8352]	0.0507 [-0.0529, 0.1543]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		6 (33.3%)	0	6 (21.4%)	10.2632 [0.4951, 212.7546]	6.5000 [0.4162, 101.5134]	0.3043 [0.0822, 0.5265]	
						0.0552		

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

Table 1.47 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

North America

Symptom	Severity	TransCon hGH (N=27)	Genotropin (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	9 (33.3%)	1 (6.7%)	10 (23.8%)	9.6923 [1.0744, 87.4369]	6.1364 [0.8652, 43.5194] 0.0231	0.3424 [0.1013, 0.5836]	0.9948
	MILD	9 (33.3%)	1 (6.7%)	10 (23.8%)	9.6923 [1.0744, 87.4369]	6.1364 [0.8652, 43.5194] 0.0231	0.3424 [0.1013, 0.5836]	0.9849
	MODERATE	0	0	0				0.9996
	SEVERE	0	0	0				
Bruising	ANY	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	1.0000
	MILD	1 (3.7%)	1 (6.7%)	2 (4.8%)	0.2148 [0.0082, 5.6405]	0.2319 [0.0101, 5.3380] 0.2259	-0.0667 [-0.1929, 0.0596]	1.0000
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9998
	MILD	1 (3.7%)	0	1 (2.4%)	2.1628 [0.0825, 56.7104]	2.0870 [0.0907, 48.0418] 0.4090	0.0455 [-0.0416, 0.1325]	0.9998
	MODERATE	0	0	0				
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 1 of 6

Table 1.47 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

North America

Symptom	Severity	TransCon hGH (N=27)	Genotropin (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	0	0	0				0.9996
	MILD	0	0	0				0.9996
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		10 (37.0%)	2 (13.3%)	12 (28.6%)	4.5000 [0.8105, 24.9856]	3.0682 [0.7684, 12.2508]	0.2758 [0.0078, 0.5437]	0.8601
					0.0755			

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ...\\biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019



Table 1.47 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

Europe

Symptom	Severity	TransCon hGH (N=66)	Genotropin (N=31)	Total (N=97)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	11 (16.7%)	1 (3.2%)	12 (12.4%)	5.3369 [0.6484, 43.9281]	4.4518 [0.6274, 31.5859]	0.1200 [0.0110, 0.2291]	
	MILD	10 (15.2%)	1 (3.2%)	11 (11.3%)	4.7534 [0.5748, 39.3131]	4.0640 [0.5689, 29.0305]	0.1065 [0.0000, 0.2130]	
	MODERATE	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]	
	SEVERE	0	0	0		0.5335		
Bruising	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	5 (7.6%)	0	5 (5.2%)	4.8202 [0.2539, 91.5060]	4.4000 [0.2550, 75.9324]	0.0674 [0.0056, 0.1293]	
	MILD	5 (7.6%)	0	5 (5.2%)	4.8202 [0.2539, 91.5060]	4.4000 [0.2550, 75.9324]	0.0674 [0.0056, 0.1293]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

Table 1.47 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

Europe

Symptom	Severity	TransCon hGH (N=66)	Genotropin (N=31)	Total (N=97)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	3 (4.5%)	0	3 (3.1%)	2.9355 [0.1447, 59.5532]	2.8000 [0.1514, 51.7839]	0.0404 [-0.0081, 0.0889]	
	MILD	3 (4.5%)	0	3 (3.1%)	2.9355 [0.1447, 59.5532]	2.8000 [0.1514, 51.7839]	0.0404 [-0.0081, 0.0889]	
	MODERATE	0	0	0		0.2735		
	SEVERE	0	0	0		0.2735		
Overall number of abnormal injection-site reactions		14 (21.2%)	1 (3.2%)	15 (15.5%)	7.2816 [0.8927, 59.3922]	5.6151 [0.8032, 39.2551]	0.1605 [0.0445, 0.2764]	
								0.0360

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

Table 1.47 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

Rest of the World

Symptom	Severity	TransCon hGH (N=12)	Genotropin (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	4 (33.3%)	0	4 (18.2%)	5.7008 [0.5288, 61.4523]	3.7690 [0.5110, 27.8018] 0.0553	0.3333 [0.0660, 0.6007]	
	MILD	4 (33.3%)	0	4 (18.2%)	5.7008 [0.5288, 61.4523]	3.7690 [0.5110, 27.8018] 0.0553	0.3333 [0.0660, 0.6007]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Bruising	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	2 (16.7%)	0	2 (9.1%)	3.0000 [0.2554, 35.2324]	2.4464 [0.3054, 19.5975] 0.2132	0.1602 [-0.0485, 0.3689]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 5 of 6

Table 1.47 Local Tolerability from Site by Maximum Severity and Symptom for Overall Study, Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

Rest of the World

Symptom	Severity	TransCon hGH (N=12)	Genotropin (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	MILD	2 (16.7%)	0	2 (9.1%)	3.0000 [0.2554, 35.2324]	2.4464 [0.3054, 19.5975]	0.1602 [-0.0485, 0.3689]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		6 (50.0%)	0	6 (27.3%)	11.2102 [1.0500, 119.6895]	5.4046 [0.7965, 36.6745]	0.4935 [0.2083, 0.7787]	0.0131

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-sub.sas  
Data Extracted: 03May2019

Table 1.48 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 at baseline Safety Population

Peak stimulated GH concentration at baseline: <8ng/mL

Symptom	Severity	TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	19 (25.0%)	2 (4.9%)	21 (17.9%)	6.7005 [1.4524, 30.9109]	5.0853 [1.2566, 20.5793] 0.0070	0.2001 [0.0835, 0.3167]	0.9797
	MILD	18 (23.7%)	2 (4.9%)	20 (17.1%)	6.2073 [1.3428, 28.6934]	4.8187 [1.1856, 19.5841] 0.0102	0.1870 [0.0718, 0.3023]	0.9798
	MODERATE	1 (1.3%)	0	1 (0.9%)	1.6387 [0.0649, 41.3846]	1.6230 [0.0680, 38.7336] 0.4652	0.0131 [-0.0125, 0.0386]	0.9808
	SEVERE	0	0	0				
Bruising	ANY	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5520 [0.0347, 8.7756]	0.5520 [0.0358, 8.5079] 0.6657	-0.0110 [-0.0654, 0.0434]	0.9988
	MILD	1 (1.3%)	1 (2.4%)	2 (1.7%)	0.5520 [0.0347, 8.7756]	0.5520 [0.0358, 8.5079] 0.6657	-0.0110 [-0.0654, 0.0434]	0.9988
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	5 (6.6%)	0	5 (4.3%)	6.4414 [0.3449, 120.3014]	5.9508 [0.3395, 104.3175] 0.0949	0.0653 [0.0097, 0.1209]	0.9986

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 1 of 4

Table 1.48 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 at baseline Safety Population

Peak stimulated GH concentration at baseline: <8ng/mL

Symptom	Severity	TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Swelling	MILD	5 (6.6%)	0	5 (4.3%)	6.4414 [0.3449, 120.3014]	5.9508 [0.3395, 104.3175] 0.0949	0.0653 [0.0097, 0.1209]	0.9986
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	3 (3.9%)	0	3 (2.6%)	3.9565 [0.1981, 79.0126]	3.7869 [0.2017, 71.1156] 0.2009	0.0392 [-0.0044, 0.0828]	0.9989
	MILD	3 (3.9%)	0	3 (2.6%)	3.9565 [0.1981, 79.0126]	3.7869 [0.2017, 71.1156] 0.2009	0.0392 [-0.0044, 0.0828]	0.9989
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Overall number of abnormal injection-site reactions		23 (30.3%)	3 (7.3%)	26 (22.2%)	5.6613 [1.5591, 20.5570]	4.1076 [1.3226, 12.7567] 0.0045	0.2283 [0.0990, 0.3576]	0.9767

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 2 of 4

Table 1.48 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 at baseline Safety Population

Peak stimulated GH concentration at baseline: >=8ng/mL

Symptom	Severity	TransCon hGH (N=29)	Genotropin (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Redness	ANY	5 (17.2%)	0	5 (11.4%)	7.4516 [0.3713, 149.5463]	5.7619 [0.3498, 94.9085]	0.1687 [0.0320, 0.3053]	
	MILD	5 (17.2%)	0	5 (11.4%)	7.4516 [0.3713, 149.5463]	5.7619 [0.3498, 94.9085]	0.1687 [0.0320, 0.3053]	
	MODERATE	0	0	0		0.0886		
	SEVERE	0	0	0				
Bruising	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.0337 [-0.0320, 0.0995]	
	MILD	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.0337 [-0.0320, 0.0995]	
	MODERATE	0	0	0		0.4795		
	SEVERE	0	0	0				

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:59 Page 3 of 4

Table 1.48 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 at baseline Safety Population

Peak stimulated GH concentration at baseline: >=8ng/mL

Symptom	Severity	TransCon hGH (N=29)	Genotropin (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Other	ANY	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265]	0.0699 [-0.0229, 0.1627]	
	MILD	2 (6.9%)	0	2 (4.5%)	1.7665 [0.1676, 18.6170]	1.6848 [0.1915, 14.8265]	0.0699 [-0.0229, 0.1627]	0.3043
	MODERATE	0	0	0				
	SEVERE	0	0	0				
	Overall number of abnormal injection-site reactions		7 (24.1%)	0	7 (15.9%)	4.7094 [0.5035, 44.0475]	3.7099 [0.4769, 28.8580]	0.2386 [0.0831, 0.3940]

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-sub.sas  
Data Extracted: 03May2019



Table 1.50 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by age  
Safety Population

Age: < 6 years

Symptom	Severity	TransCon hGH (N=25)	Genotropin (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	18 (72.0%)	12 (85.7%)	30 (76.9%)	0.4286 [0.0758, 2.4245]	0.8400 [0.6071, 1.1623]	-0.1371 [-0.3913, 0.1170]	0.1151
	HURTS LITTLE BIT	7 (28.0%)	2 (14.3%)	9 (23.1%)	2.3333 [0.4125, 13.2001]	1.9600 [0.4696, 8.1804]	0.1371 [-0.1170, 0.3913]	0.6023
	HURTS LITTLE MORE	3 (12.0%)	4 (28.6%)	7 (17.9%)	0.3409 [0.0640, 1.8168]	0.4200 [0.1093, 1.6143]	-0.1657 [-0.4345, 0.1030]	0.0622
	HURTS EVEN MORE	4 (16.0%)	3 (21.4%)	7 (17.9%)	0.6984 [0.1321, 3.6924]	0.7467 [0.1943, 2.8699]	-0.0543 [-0.3128, 0.2043]	0.2811
	HURTS WHOLE LOT	2 (8.0%)	0	2 (5.1%)	3.0851 [0.1381, 68.9025]	2.8846 [0.1481, 56.1771]	0.0800 [-0.0263, 0.1863]	0.9747
	HURTS WORST	2 (8.0%)	3 (21.4%)	5 (12.8%)	0.3188 [0.0464, 2.1924]	0.3733 [0.0706, 1.9739]	-0.1343 [-0.3741, 0.1055]	0.2629
Itching	ANY	6 (24.0%)	4 (28.6%)	10 (25.6%)	0.7895 [0.1799, 3.4641]	0.8400 [0.2844, 2.4806]	-0.0457 [-0.3356, 0.2442]	0.4127
	ITCHES A LITTLE	5 (20.0%)	3 (21.4%)	8 (20.5%)	0.9167 [0.1833, 4.5830]	0.9333 [0.2613, 3.3337]	-0.0143 [-0.2803, 0.2518]	0.2328

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 1 of 4

Table 1.50 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by age  
Safety Population

Age: < 6 years

Symptom	Severity	TransCon hGH (N=25)	Genotropin (N=14)	Total (N=39)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	0	1 (7.1%)	1 (2.6%)	0.1765 [0.0067, 4.6334]	0.1923 [0.0083, 4.4292]	-0.0714 [-0.2063, 0.0635]	0.9808
	ITCHES WORSE	1 (4.0%)	0	1 (2.6%)	1.7755 [0.0678, 46.5214]	1.7308 [0.0751, 39.8631]	0.0400 [-0.0368, 0.1168]	0.9745
Overall number of abnormal injection-site reactions		18 (72.0%)	12 (85.7%)	30 (76.9%)	0.4286 [0.0758, 2.4245]	0.8400 [0.6071, 1.1623]	-0.1371 [-0.3913, 0.1170]	0.1089
					0.3358			

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 2 of 4

Table 1.50 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by age  
Safety Population

Age: >=6 years

Symptom	Severity	TransCon hGH (N=80)	Genotropin (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	58 (72.5%)	24 (57.1%)	82 (67.2%)	1.9773 [0.9030, 4.3297]	1.2688 [0.9450, 1.7035]	0.1536 [-0.0252, 0.3324]	
	HURTS LITTLE BIT	22 (27.5%)	9 (21.4%)	31 (25.4%)	1.3908 [0.5737, 3.3715]	1.2833 [0.6504, 2.5323]	0.0607 [-0.0973, 0.2187]	
	HURTS LITTLE MORE	16 (20.0%)	4 (9.5%)	20 (16.4%)	2.3750 [0.7394, 7.6283]	2.1000 [0.7497, 5.8825]	0.1048 [-0.0200, 0.2295]	
	HURTS EVEN MORE	2 (2.5%)	5 (11.9%)	7 (5.7%)	0.1897 [0.0352, 1.0241]	0.2100 [0.0425, 1.0367]	-0.0940 [-0.1978, 0.0097]	
	HURTS WHOLE LOT	11 (13.8%)	3 (7.1%)	14 (11.5%)	2.0725 [0.5450, 7.8802]	1.9250 [0.5679, 6.5252]	0.0661 [-0.0424, 0.1745]	
	HURTS WORST	7 (8.8%)	3 (7.1%)	10 (8.2%)	1.2466 [0.3052, 5.0920]	1.2250 [0.3339, 4.4945]	0.0161 [-0.0834, 0.1156]	
Itching	ANY	29 (36.3%)	11 (26.2%)	40 (32.8%)	1.6025 [0.7021, 3.6574]	1.3841 [0.7711, 2.4844]	0.1006 [-0.0690, 0.2702]	
	ITCHES A LITTLE	26 (32.5%)	6 (14.3%)	32 (26.2%)	2.8889 [1.0812, 7.7187]	2.2750 [1.0168, 5.0900]	0.1821 [0.0347, 0.3296]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 3 of 4

Table 1.50 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by age  
Safety Population

Age: >=6 years

Symptom	Severity	TransCon hGH (N=80)	Genotropin (N=42)	Total (N=122)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	1 (1.3%)	3 (7.1%)	4 (3.3%)	0.1646 [0.0166, 1.6339]	0.1750 [0.0188, 1.6310] 0.0837	-0.0589 [-0.1405, 0.0227]	
	ITCHES WORSE	2 (2.5%)	2 (4.8%)	4 (3.3%)	0.5128 [0.0696, 3.7767]	0.5250 [0.0767, 3.5955] 0.5068	-0.0226 [-0.0955, 0.0503]	
Overall number of abnormal injection-site reactions		60 (75.0%)	25 (59.5%)	85 (69.7%)	2.0400 [0.9191, 4.5280]	1.2600 [0.9526, 1.6666]	0.1548 [-0.0214, 0.3309]	0.0785

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 4 of 4

Table 1.51 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by gender  
Safety Population

Male

Symptom	Severity	TransCon hGH (N=86)	Genotropin (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	61 (70.9%)	31 (67.4%)	92 (69.7%)	1.2003 [0.5545, 2.5984]	1.0581 [0.8284, 1.3516]	0.0390 [-0.1273, 0.2053]	0.2159
	HURTS LITTLE BIT	24 (27.9%)	10 (21.7%)	34 (25.8%)	1.3922 [0.6007, 3.2262]	1.2843 [0.6753, 2.4422]	0.0622 [-0.0911, 0.2154]	0.5047
	HURTS LITTLE MORE	15 (17.4%)	7 (15.2%)	22 (16.7%)	1.1945 [0.4484, 3.1823]	1.1631 [0.5005, 2.7029]	0.0243 [-0.1070, 0.1557]	0.5822
	HURTS EVEN MORE	4 (4.7%)	6 (13.0%)	10 (7.6%)	0.3330 [0.0874, 1.2688]	0.3743 [0.1131, 1.2383]	-0.0804 [-0.1862, 0.0255]	0.7728
	HURTS WHOLE LOT	10 (11.6%)	3 (6.5%)	13 (9.8%)	1.8418 [0.4806, 7.0584]	1.7382 [0.5111, 5.9114]	0.0491 [-0.0495, 0.1477]	0.9769
	HURTS WORST	8 (9.3%)	5 (10.9%)	13 (9.8%)	0.8355 [0.2563, 2.7236]	0.8494 [0.2893, 2.4943]	-0.0162 [-0.1251, 0.0927]	0.7437
Itching	ANY	30 (34.9%)	12 (26.1%)	42 (31.8%)	1.5018 [0.6780, 3.3266]	1.3264 [0.7533, 2.3355]	0.0853 [-0.0766, 0.2473]	0.5300
	ITCHES A LITTLE	26 (30.2%)	8 (17.4%)	34 (25.8%)	2.0367 [0.8346, 4.9698]	1.7226 [0.8491, 3.4949]	0.1260 [-0.0203, 0.2723]	0.7238

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 1 of 4

Table 1.51 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by gender  
Safety Population

Male

Symptom	Severity	TransCon hGH (N=86)	Genotropin (N=46)	Total (N=132)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	1 (1.2%)	2 (4.3%)	3 (2.3%)	0.2570 [0.0222, 2.9769]	0.2629 [0.0227, 3.0391]	-0.0316 [-0.0944, 0.0312]	0.9766
	ITCHES WORSE	3 (3.5%)	2 (4.3%)	5 (3.8%)	0.7894 [0.1295, 4.8123]	0.2516 0.7959 [0.1414, 4.4807]	-0.0090 [-0.0804, 0.0623]	0.9994
Overall number of abnormal injection-site reactions		63 (73.3%)	32 (69.6%)	95 (72.0%)	1.2106 [0.5516, 2.6569]	1.0567 [0.8371, 1.3340]	0.0393 [-0.1241, 0.2027]	0.2239
					0.6339			

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 2 of 4

Table 1.51 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by gender  
Safety Population

Female

Symptom	Severity	TransCon hGH (N=19)	Genotropin (N=10)	Total (N=29)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	15 (78.9%)	5 (50.0%)	20 (69.0%)	3.5714 [0.6802, 18.7525]	1.5455 [0.8156, 2.9286]	0.2802 [-0.0867, 0.6470]	
	HURTS LITTLE BIT	5 (26.3%)	1 (10.0%)	6 (20.7%)	4.0000 [0.3854, 41.5115]	3.0000 [0.4135, 21.7635]	0.1946 [-0.0778, 0.4670]	
	HURTS LITTLE MORE	4 (21.1%)	1 (10.0%)	5 (17.2%)	2.9091 [0.2711, 31.2138]	2.4000 [0.3154, 18.2648]	0.1362 [-0.1269, 0.3993]	
	HURTS EVEN MORE	2 (10.5%)	2 (20.0%)	4 (13.8%)	0.3200 [0.0277, 3.6948]	0.3200 [0.0273, 3.7519]	-0.1323 [-0.4147, 0.1501]	
	HURTS WHOLE LOT	3 (15.8%)	0	3 (10.3%)	5.3200 [0.2443, 115.8629]	4.3750 [0.2516, 76.0826]	0.1751 [0.0016, 0.3486]	
	HURTS WORST	1 (5.3%)	1 (10.0%)	2 (6.9%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0458, 1.3649]	-0.0934 [-0.2692, 0.0824]	
Itching	ITCHES WORSE	0	0	0				
	ANY	5 (26.3%)	3 (30.0%)	8 (27.6%)	0.8929 [0.1861, 4.2829]	0.9146 [0.2822, 2.9649]	-0.0272 [-0.4073, 0.3528]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 3 of 4

Table 1.51 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by gender  
Safety Population

Female

Symptom	Severity	TransCon hGH (N=19)	Genotropin (N=10)	Total (N=29)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES A LITTLE	5 (26.3%)	1 (10.0%)	6 (20.7%)	2.3438 [0.3173, 17.3131]	2.3438 [0.3697, 14.8591]	0.1673 [-0.1625, 0.4972]	
	ITCHES EVEN MORE	0	2 (20.0%)	2 (6.9%)	0.0968 [0.0041, 2.2788]	0.1250 [0.0067, 2.3451]	-0.1946 [-0.4417, 0.0526]	0.0619
Overall number of abnormal injection-site reactions		15 (78.9%)	5 (50.0%)	20 (69.0%)	3.5714 [0.6802, 18.7525]	1.5455 [0.8156, 2.9286]	0.2802 [-0.0867, 0.6470]	0.1369

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 4 of 4



Table 1.52 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  
Safety Population

Baseline GH-stimulation strata: <=5ng/mL

Symptom	Severity	TransCon hGH (N=37)	Genotropin (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	33 (89.2%)	13 (61.9%)	46 (79.3%)	4.8649 [1.2641, 18.7229]	1.4281 [1.0085, 2.0223] 0.0169	0.2678 [0.0356, 0.5000]	0.0346
	HURTS LITTLE BIT	10 (27.0%)	6 (28.6%)	16 (27.6%)	0.9194 [0.2783, 3.0373]	0.9412 [0.3988, 2.2214] 0.8922	-0.0169 [-0.2577, 0.2240]	0.2627
	HURTS LITTLE MORE	10 (27.0%)	1 (4.8%)	11 (19.0%)	7.4909 [0.8747, 64.1520]	5.7600 [0.7730, 42.9223] 0.0412	0.2228 [0.0532, 0.3925]	0.0411
	HURTS EVEN MORE	3 (8.1%)	3 (14.3%)	6 (10.3%)	0.4293 [0.0686, 2.6877]	0.5000 [0.1132, 2.2075] 0.3660	-0.0730 [-0.2394, 0.0934]	0.5748
	HURTS WHOLE LOT	8 (21.6%)	0	8 (13.8%)	13.9778 [0.7556, 258.5821]	10.4194 [0.6372, 170.3883] 0.0176	0.2247 [0.0904, 0.3590]	0.9633
	HURTS WORST	2 (5.4%)	3 (14.3%)	5 (8.6%)	0.3571 [0.0577, 2.2122]	0.3846 [0.0723, 2.0470] 0.2499	-0.0899 [-0.2600, 0.0802]	0.2891
Itching	ANY	12 (32.4%)	6 (28.6%)	18 (31.0%)	1.1886 [0.3830, 3.6884]	1.1346 [0.4992, 2.5790] 0.7602	0.0393 [-0.2154, 0.2940]	0.7840

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 1 of 4

Table 1.52 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  
Safety Population

Baseline GH-stimulation strata: <=5ng/mL

Symptom	Severity	TransCon hGH (N=37)	Genotropin (N=21)	Total (N=58)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES A LITTLE	12 (32.4%)	4 (19.0%)	16 (27.6%)	1.8912 [0.5509, 6.4919]	1.6698 [0.6177, 4.5137] 0.2852	0.1330 [-0.1062, 0.3721]	0.8785
	ITCHES EVEN MORE	0	0	0				0.9953
	ITCHES WORSE	0	2 (9.5%)	2 (3.4%)	0.1082 [0.0049, 2.3895]	0.1226 [0.0062, 2.4186]	-0.0936 [-0.2185, 0.0312]	0.9429
Overall number of abnormal injection-site reactions		33 (89.2%)	13 (61.9%)	46 (79.3%)	4.8649 [1.2641, 18.7229]	1.4281 [1.0085, 2.0223]	0.2678 [0.0356, 0.5000]	0.0356
					0.0169			

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 2 of 4

Table 1.52 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  
Safety Population

Baseline GH-stimulation strata: >5ng/mL

Symptom	Severity	TransCon hGH (N=68)	Genotropin (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	43 (63.2%)	23 (65.7%)	66 (64.1%)	0.9194 [0.3896, 2.1695]	0.9708 [0.7177, 1.3130]	-0.0191 [-0.2133, 0.1751]	
	HURTS LITTLE BIT	19 (27.9%)	5 (14.3%)	24 (23.3%)	2.3005 [0.7783, 6.8000]	1.9369 [0.7941, 4.7246]	0.1351 [-0.0230, 0.2933]	
	HURTS LITTLE MORE	9 (13.2%)	7 (20.0%)	16 (15.5%)	0.6205 [0.2120, 1.8166]	0.6594 [0.2560, 1.6986]	-0.0667 [-0.2234, 0.0901]	
	HURTS EVEN MORE	3 (4.4%)	5 (14.3%)	8 (7.8%)	0.2927 [0.0650, 1.3183]	0.3313 [0.0873, 1.2579]	-0.0948 [-0.2204, 0.0307]	
	HURTS WHOLE LOT	5 (7.4%)	3 (8.6%)	8 (7.8%)	0.8449 [0.1952, 3.6574]	0.8543 [0.2216, 3.2937]	-0.0128 [-0.1268, 0.1011]	
	HURTS WORST	7 (10.3%)	3 (8.6%)	10 (9.7%)	1.2706 [0.3021, 5.3438]	1.2416 [0.3337, 4.6203]	0.0201 [-0.0964, 0.1366]	
Itching	ANY	23 (33.8%)	9 (25.7%)	32 (31.1%)	1.4494 [0.5813, 3.6139]	1.2953 [0.6762, 2.4811]	0.0765 [-0.1065, 0.2595]	
	ITCHES A LITTLE	19 (27.9%)	5 (14.3%)	24 (23.3%)	2.2881 [0.7704, 6.7954]	1.9204 [0.7871, 4.6851]	0.1327 [-0.0247, 0.2901]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 3 of 4

Table 1.52 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  
Safety Population

Baseline GH-stimulation strata: >5ng/mL

Symptom	Severity	TransCon hGH (N=68)	Genotropin (N=35)	Total (N=103)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	1 (1.5%)	4 (11.4%)	5 (4.9%)	0.1088 [0.0113, 1.0478]	0.1225 [0.0137, 1.0937]	-0.1008 [-0.2101, 0.0084]	
	ITCHES WORSE	3 (4.4%)	0	3 (2.9%)	2.2498 [0.2383, 21.2441]	0.0251 2.1658 [0.2495, 18.8034]	0.0446 [-0.0046, 0.0938]	
Overall number of abnormal injection-site reactions		45 (66.2%)	24 (68.6%)	69 (67.0%)	0.9120 [0.3810, 2.1831]	0.9703 [0.7301, 1.2895]	-0.0203 [-0.2113, 0.1708]	0.8371

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 4 of 4

Table 1.53 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  
Safety Population

Isolated idiopathic

Symptom	Severity	TransCon hGH (N=68)	Genotropin (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	50 (73.5%)	29 (78.4%)	79 (75.2%)	0.7721 [0.3019, 1.9749]	0.9382 [0.7484, 1.1763]	-0.0483 [-0.2196, 0.1231]	0.0771
	HURTS LITTLE BIT	19 (27.9%)	9 (24.3%)	28 (26.7%)	1.1893 [0.4749, 2.9782]	1.1363 [0.5764, 2.2402]	0.0335 [-0.1416, 0.2086]	0.6032
	HURTS LITTLE MORE	13 (19.1%)	6 (16.2%)	19 (18.1%)	1.2237 [0.4285, 3.4948]	1.1904 [0.4750, 2.9829]	0.0302 [-0.1233, 0.1837]	0.9777
	HURTS EVEN MORE	4 (5.9%)	7 (18.9%)	11 (10.5%)	0.2753 [0.0750, 1.0108]	0.3184 [0.1009, 1.0050]	-0.1290 [-0.2675, 0.0095]	0.9146
	HURTS WHOLE LOT	9 (13.2%)	3 (8.1%)	12 (11.4%)	1.6950 [0.4286, 6.7031]	1.5977 [0.4677, 5.4580]	0.0493 [-0.0700, 0.1686]	0.9993
	HURTS WORST	5 (7.4%)	4 (10.8%)	9 (8.6%)	0.6733 [0.1697, 2.6723]	0.6936 [0.1907, 2.5222]	-0.0323 [-0.1498, 0.0853]	0.8151
Itching	ANY	24 (35.3%)	11 (29.7%)	35 (33.3%)	1.2759 [0.5374, 3.0294]	1.1784 [0.6525, 2.1284]	0.0531 [-0.1326, 0.2389]	0.4133
	ITCHES A LITTLE	21 (30.9%)	6 (16.2%)	27 (25.7%)	2.2804 [0.8280, 6.2806]	1.8934 [0.8341, 4.2980]	0.1446 [-0.0174, 0.3066]	0.4846

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 1 of 6

Table 1.53 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  
Safety Population

Isolated idiopathic

Symptom	Severity	TransCon hGH (N=68)	Genotropin (N=37)	Total (N=105)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	1 (1.5%)	4 (10.8%)	5 (4.8%)	0.1185 [0.0124, 1.1274]	0.1319 [0.0149, 1.1645]	-0.0941 [-0.1981, 0.0099]	1.0000
	ITCHES WORSE	2 (2.9%)	1 (2.7%)	3 (2.9%)	1.0985 [0.0995, 12.1221]	0.0317 1.0966 [0.1064, 11.3030]	0.0027 [-0.0643, 0.0696]	0.8974
Overall number of abnormal injection-site reactions		51 (75.0%)	30 (81.1%)	81 (77.1%)	0.7037 [0.2649, 1.8691]	0.9240 [0.7474, 1.1424]	-0.0615 [-0.2265, 0.1036]	0.0442
					0.4783			

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 2 of 6

Table 1.53 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  
Safety Population

Isolated organic (determined by abnormal MRI)

Symptom	Severity	TransCon hGH (N=19)	Genotropin (N=9)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	12 (63.2%)	2 (22.2%)	14 (50.0%)	5.2500 [0.8006, 34.4259]	2.7000 [0.7431, 9.8105] 0.0783	0.3778 [0.0100, 0.7455]	
	HURTS LITTLE BIT	6 (31.6%)	1 (11.1%)	7 (25.0%)	4.0000 [0.3854, 41.5115]	3.0000 [0.4135, 21.7635] 0.2334	0.2222 [-0.0925, 0.5370]	
	HURTS LITTLE MORE	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
	HURTS EVEN MORE	1 (5.3%)	0	1 (3.6%)			0.0000 [0.0000, 0.0000]	
	HURTS WHOLE LOT	1 (5.3%)	0	1 (3.6%)	1.9655 [0.0722, 53.4778]	1.8750 [0.0843, 41.6860] 0.4386	0.0667 [-0.0596, 0.1929]	
	HURTS WORST	3 (15.8%)	1 (11.1%)	4 (14.3%)	1.2308 [0.0954, 15.8721]	1.2000 [0.1260, 11.4277] 0.8760	0.0222 [-0.2456, 0.2901]	
Itching	ITCHES EVEN MORE	0	0	0				
	ANY	7 (36.8%)	1 (11.1%)	8 (28.6%)	5.3333 [0.5234, 54.3441]	3.6000 [0.5127, 25.2791] 0.1400	0.2889 [-0.0330, 0.6108]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 3 of 6

Table 1.53 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  
Safety Population

Isolated organic (determined by abnormal MRI)

Symptom	Severity	TransCon hGH (N=19)	Genotropin (N=9)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES A LITTLE	6 (31.6%)	0	6 (21.4%)	9.9524 [0.4832, 204.9918]	6.8750 [0.4243, 111.3918] 0.0567	0.3333 [0.0948, 0.5719]	
	ITCHES WORSE	1 (5.3%)	1 (11.1%)	2 (7.1%)	0.5714 [0.0313, 10.4345]	0.6000 [0.0426, 8.4564] 0.7089	-0.0444 [-0.2855, 0.1966]	
Overall number of abnormal injection-site reactions		13 (68.4%)	2 (22.2%)	15 (53.6%)	7.0000 [1.0437, 46.9485]	3.0000 [0.8395, 10.7206]	0.4444 [0.0829, 0.8059]	0.0390

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 4 of 6



Table 1.53 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  
Safety Population

Multiple pituitary hormone deficiencies

Symptom	Severity	TransCon hGH (N=18)	Genotropin (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	14 (77.8%)	5 (50.0%)	19 (67.9%)	4.5833 [0.7458, 28.1671]	1.6418 [0.8389, 3.2131]	0.3116 [-0.0394, 0.6626]	
	HURTS LITTLE BIT	4 (22.2%)	1 (10.0%)	5 (17.9%)	3.8636 [0.2546, 58.6411]	2.9091 [0.2976, 28.4409]	0.1522 [-0.0963, 0.4006]	
	HURTS LITTLE MORE	5 (27.8%)	2 (20.0%)	7 (25.0%)	1.4091 [0.2269, 8.7490]	1.3000 [0.3290, 5.1365]	0.0652 [-0.2722, 0.4026]	
	HURTS EVEN MORE	1 (5.6%)	1 (10.0%)	2 (7.1%)	1.0000 [0.0335, 29.8074]	1.0000 [0.1040, 9.6135]	0.0000 [-0.1804, 0.1804]	
	HURTS WHOLE LOT	3 (16.7%)	0	3 (10.7%)	4.2000 [0.1895, 93.0809]	3.5000 [0.2047, 59.8483]	0.1522 [-0.0187, 0.3230]	
	HURTS WORST	1 (5.6%)	1 (10.0%)	2 (7.1%)	0.4286 [0.0228, 8.0435]	0.4667 [0.0339, 6.4267]	-0.0580 [-0.2753, 0.1594]	
Itching	ITCHES EVEN MORE	0	0	0				
	ITCHES WORSE	0	0	0				
	ANY	4 (22.2%)	3 (30.0%)	7 (25.0%)	0.6061 [0.1007, 3.6471]	0.6829 [0.1706, 2.7339]	-0.0942 [-0.4384, 0.2500]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 5 of 6

Table 1.53 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  
Safety Population

Multiple pituitary hormone deficiencies

Symptom	Severity	TransCon hGH (N=18)	Genotropin (N=10)	Total (N=28)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES A LITTLE	4 (22.2%)	3 (30.0%)	7 (25.0%)	0.6061 [0.1007, 3.6471]	0.6829 [0.1706, 2.7339]	-0.0942 [-0.4384, 0.2500]	
Overall number of abnormal injection-site reactions		14 (77.8%)	5 (50.0%)	19 (67.9%)	4.5833 [0.7458, 28.1671]	1.6418 [0.8389, 3.2131]	0.3116 [-0.0394, 0.6626]	0.0994

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 6 of 6

Table 1.54 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

North America

Symptom	Severity	TransCon hGH (N=27)	Genotropin (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	23 (85.2%)	14 (93.3%)	37 (88.1%)	0.7143 [0.0589, 8.6647]	0.9740 [0.8062, 1.1768]	-0.0242 [-0.1985, 0.1500]	0.1473
	HURTS LITTLE BIT	8 (29.6%)	5 (33.3%)	13 (31.0%)	1.1429 [0.2872, 4.5470]	1.0909 [0.4416, 2.6948]	0.0303 [-0.2817, 0.3423]	0.4460
	HURTS LITTLE MORE	3 (11.1%)	1 (6.7%)	4 (9.5%)	1.4000 [0.1154, 16.9828]	1.3636 [0.1355, 13.7241]	0.0242 [-0.1500, 0.1985]	0.9723
	HURTS EVEN MORE	2 (7.4%)	5 (33.3%)	7 (16.7%)	0.0952 [0.0098, 0.9267]	0.1364 [0.0177, 1.0532]	-0.2879 [-0.5418, -0.0339]	0.7151
	HURTS WHOLE LOT	5 (18.5%)	2 (13.3%)	7 (16.7%)	1.9118 [0.3186, 11.4709]	1.7045 [0.3793, 7.6604]	0.0939 [-0.1515, 0.3394]	0.7668
	HURTS WORST	5 (18.5%)	1 (6.7%)	6 (14.3%)	3.1111 [0.3119, 31.0283]	2.7273 [0.3371, 22.0657]	0.1152 [-0.0896, 0.3199]	0.1328
Itching	ANY	11 (40.7%)	6 (40.0%)	17 (40.5%)	1.0385 [0.2725, 3.9568]	1.0227 [0.4606, 2.2709]	0.0091 [-0.3129, 0.3311]	0.6897
	ITCHES A LITTLE	9 (33.3%)	2 (13.3%)	11 (26.2%)	3.7143 [0.6627, 20.8174]	2.7273 [0.6701, 11.1000]	0.2303 [-0.0343, 0.4949]	0.4484

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 1 of 6

Table 1.54 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

North America

Symptom	Severity	TransCon hGH (N=27)	Genotropin (N=15)	Total (N=42)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	0	3 (20.0%)	3 (7.1%)	0.0794 [0.0038, 1.6638]	0.0994 [0.0055, 1.7947]	-0.2000 [-0.4024, 0.0024]	0.9987
	ITCHES WORSE	2 (7.4%)	1 (6.7%)	3 (7.1%)	0.6667 [0.0384, 11.5611]	0.6818 [0.0461, 10.0744]	-0.0212 [-0.1745, 0.1321]	0.9987
Overall number of abnormal injection-site reactions		23 (85.2%)	14 (93.3%)	37 (88.1%)	0.7143 [0.0589, 8.6647]	0.9740 [0.8062, 1.1768]	-0.0242 [-0.1985, 0.1500]	0.0750
					0.7936			

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

Table 1.54 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

Europe

Symptom	Severity	TransCon hGH (N=66)	Genotropin (N=31)	Total (N=97)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	43 (65.2%)	18 (58.1%)	61 (62.9%)	1.5694 [0.6384, 3.8583]	1.1858 [0.8216, 1.7113]	0.1030 [-0.1030, 0.3090]	
	HURTS LITTLE BIT	17 (25.8%)	5 (16.1%)	22 (22.7%)	1.9125 [0.6296, 5.8101]	1.6665 [0.6811, 4.0771]	0.1072 [-0.0618, 0.2763]	
	HURTS LITTLE MORE	13 (19.7%)	5 (16.1%)	18 (18.6%)	1.2627 [0.4003, 3.9828]	1.2192 [0.4451, 3.3397]	0.0338 [-0.1279, 0.1956]	
	HURTS EVEN MORE	3 (4.5%)	3 (9.7%)	6 (6.2%)	0.5801 [0.0988, 3.4043]	0.6295 [0.1345, 2.9464]	-0.0314 [-0.1401, 0.0772]	
	HURTS WHOLE LOT	8 (12.1%)	1 (3.2%)	9 (9.3%)	3.8204 [0.4698, 31.0664]	3.4750 [0.4890, 24.6948]	0.0861 [-0.0170, 0.1891]	
	HURTS WORST	2 (3.0%)	4 (12.9%)	6 (6.2%)	0.2161 [0.0354, 1.3198]	0.2254 [0.0337, 1.5074]	-0.0927 [-0.2158, 0.0305]	
Itching	ANY	19 (28.8%)	7 (22.6%)	26 (26.8%)	1.3559 [0.4977, 3.6936]	1.2675 [0.5635, 2.8511]	0.0582 [-0.1273, 0.2436]	
	ITCHES A LITTLE	17 (25.8%)	6 (19.4%)	23 (23.7%)	1.4120 [0.4895, 4.0726]	1.3144 [0.5525, 3.1271]	0.0595 [-0.1162, 0.2352]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 3 of 6

Table 1.54 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

Europe

Symptom	Severity	TransCon hGH (N=66)	Genotropin (N=31)	Total (N=97)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	1 (1.5%)	1 (3.2%)	2 (2.1%)	0.4766 [0.0238, 9.5351]	0.4766 [0.0189, 12.0087]	-0.0148 [-0.0805, 0.0509]	
	ITCHES WORSE	1 (1.5%)	0	1 (1.0%)	1.2062 [0.0471, 30.9054]	1.2000 [0.0510, 28.2372]	0.0135 [-0.0149, 0.0418]	
Overall number of abnormal injection-site reactions		44 (66.7%)	19 (61.3%)	63 (64.9%)	1.4347 [0.5825, 3.5334]	1.1387 [0.8050, 1.6106]	0.0817 [-0.1238, 0.2872]	0.4277

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 4 of 6

Table 1.54 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

Rest of the World

Symptom	Severity	TransCon hGH (N=12)	Genotropin (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	HURTS WHOLE LOT	0	0	0				
	ANY	10 (83.3%)	4 (40.0%)	14 (63.6%)	7.5333 [0.9894, 57.3585]	2.0538 [0.9279, 4.5458]	0.4242 [0.0547, 0.7938]	
	HURTS LITTLE BIT	4 (33.3%)	1 (10.0%)	5 (22.7%)	4.6333 [0.4124, 52.0503]	3.4222 [0.4360, 26.8634]	0.2359 [-0.0882, 0.5601]	
	HURTS LITTLE MORE	3 (25.0%)	2 (20.0%)	5 (22.7%)	1.2963 [0.1943, 8.6481]	1.2500 [0.2528, 6.1796]	0.0519 [-0.3228, 0.4267]	
	HURTS EVEN MORE	1 (8.3%)	0	1 (4.5%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878]	0.0736 [-0.0752, 0.2224]	
	HURTS WORST	2 (16.7%)	1 (10.0%)	3 (13.6%)	1.7250 [0.1364, 21.8190]	1.6444 [0.1522, 17.7628]	0.0628 [-0.2210, 0.3466]	
Itching	ITCHES EVEN MORE	0	0	0				
	ANY	5 (41.7%)	2 (20.0%)	7 (31.8%)	3.0800 [0.4242, 22.3647]	2.1556 [0.5223, 8.8965]	0.2251 [-0.1419, 0.5921]	
	ITCHES A LITTLE	5 (41.7%)	1 (10.0%)	6 (27.3%)	6.9600 [0.6165, 78.5792]	4.3111 [0.5871, 31.6581]	0.3225 [-0.0089, 0.6540]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 5 of 6

Table 1.54 Local Tolerability from Patient Diary by Maximum Severity and Symptom for Overall Study  
Summary of Subjects with Injection Related Events, subgroup analysis by region  
Safety Population

Rest of the World

Symptom	Severity	TransCon hGH (N=12)	Genotropin (N=10)	Total (N=22)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES WORSE	0	1 (10.0%)	1 (4.5%)	0.2632 [0.0093, 7.4315]	0.3000 [0.0139, 6.4710]	-0.0974 [-0.2817, 0.0869]	0.2888
Overall number of abnormal injection-site reactions		11 (91.7%)	4 (40.0%)	15 (68.2%)	16.7333 [1.4320, 195.5325]	2.2688 [1.0476, 4.9136]	0.5108 [0.1682, 0.8535]	0.0137

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 6 of 6



Table 1.55 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 at baseline  
Safety Population

Peak stimulated GH concentration at baseline: <8ng/mL

Symptom	Severity	TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	56 (73.7%)	27 (65.9%)	83 (70.9%)	1.4650 [0.6428, 3.3389]	1.1214 [0.8660, 1.4523]	0.0798 [-0.0955, 0.2551]	0.9793
	HURTS LITTLE BIT	20 (26.3%)	8 (19.5%)	28 (23.9%)	1.4702 [0.5821, 3.7137]	1.3458 [0.6517, 2.7793]	0.0676 [-0.0889, 0.2241]	0.8227
	HURTS LITTLE MORE	14 (18.4%)	7 (17.1%)	21 (17.9%)	1.0970 [0.4069, 2.9572]	1.0806 [0.4690, 2.4900]	0.0137 [-0.1319, 0.1593]	0.4357
	HURTS EVEN MORE	4 (5.3%)	7 (17.1%)	11 (9.4%)	0.2591 [0.0688, 0.9764]	0.3126 [0.0995, 0.9818]	-0.1169 [-0.2406, 0.0068]	0.3464
	HURTS WHOLE LOT	12 (15.8%)	1 (2.4%)	13 (11.1%)	7.5248 [0.9370, 60.4284]	6.4373 [0.8723, 47.5055]	0.1332 [0.0387, 0.2276]	0.0357
	HURTS WORST	6 (7.9%)	4 (9.8%)	10 (8.5%)	0.7976 [0.2088, 3.0466]	0.8170 [0.2468, 2.7047]	-0.0178 [-0.1258, 0.0903]	0.9626
Itching	ANY	23 (30.3%)	11 (26.8%)	34 (29.1%)	1.1821 [0.5078, 2.7518]	1.1277 [0.6114, 2.0801]	0.0342 [-0.1366, 0.2050]	0.5453
	ITCHES A LITTLE	20 (26.3%)	7 (17.1%)	27 (23.1%)	1.7261 [0.6625, 4.4977]	1.5400 [0.7087, 3.3463]	0.0921 [-0.0602, 0.2444]	0.3987

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevsym-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 1 of 4

Table 1.55 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 at baseline  
Safety Population

Peak stimulated GH concentration at baseline: <8ng/mL

Symptom	Severity	TransCon hGH (N=76)	Genotropin (N=41)	Total (N=117)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	1 (1.3%)	2 (4.9%)	3 (2.6%)	0.2630 [0.0234, 2.9610]	0.2692 [0.0245, 2.9635]	-0.0355 [-0.1063, 0.0353]	0.9759
	ITCHES WORSE	2 (2.6%)	2 (4.9%)	4 (3.4%)	0.5349 [0.0739, 3.8695]	0.5427 [0.0793, 3.7144]	-0.0224 [-0.0982, 0.0534]	0.9740
Overall number of abnormal injection-site reactions		56 (73.7%)	28 (68.3%)	84 (71.8%)	1.3105 [0.5694, 3.0162]	1.0812 [0.8433, 1.3860]	0.0553 [-0.1178, 0.2284]	0.5526
					0.5246			

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 2 of 4

Table 1.55 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 at baseline  
Safety Population

Peak stimulated GH concentration at baseline: >=8ng/mL

Symptom	Severity	TransCon hGH (N=29)	Genotropin (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Pain	ANY	20 (69.0%)	9 (60.0%)	29 (65.9%)	1.4780 [0.4034, 5.4158]	1.1486 [0.7105, 1.8569]	0.0892 [-0.2107, 0.3890]	
	HURTS LITTLE BIT	9 (31.0%)	3 (20.0%)	12 (27.3%)	1.8042 [0.4066, 8.0052]	1.5542 [0.4932, 4.8980]	0.1108 [-0.1526, 0.3743]	
	HURTS LITTLE MORE	5 (17.2%)	1 (6.7%)	6 (13.6%)	2.8333 [0.3047, 26.3493]	2.6296 [0.3143, 22.0028]	0.1060 [-0.0834, 0.2954]	
	HURTS EVEN MORE	2 (6.9%)	1 (6.7%)	3 (6.8%)	1.0714 [0.1003, 11.4413]	1.0714 [0.1027, 11.1735]	0.0048 [-0.1592, 0.1688]	
	HURTS WHOLE LOT	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2105 [0.0166, 2.6657]	0.2500 [0.0256, 2.4375]	-0.1012 [-0.2837, 0.0813]	
	HURTS WORST	3 (10.3%)	2 (13.3%)	5 (11.4%)	0.7441 [0.1122, 4.9354]	0.7636 [0.1356, 4.3009]	-0.0313 [-0.2382, 0.1755]	
Itching	ANY	12 (41.4%)	4 (26.7%)	16 (36.4%)	1.9365 [0.4872, 7.6977]	1.5315 [0.6012, 3.9014]	0.1422 [-0.1407, 0.4250]	
	ITCHES A LITTLE	11 (37.9%)	2 (13.3%)	13 (29.5%)	3.7747 [0.7327, 19.4465]	2.8364 [0.7021, 11.4581]	0.2434 [-0.0068, 0.4935]	

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 3 of 4

Table 1.55 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 at baseline  
Safety Population

Peak stimulated GH concentration at baseline:  $\geq 8$ ng/mL

Symptom	Severity	TransCon hGH (N=29)	Genotropin (N=15)	Total (N=44)	Lonapegsomatropin vs. Genotropina <sup>a</sup>			Subgroup Interaction p-value
					OR [95%-CI] <sup>b</sup>	RR [95%-CI] <sup>b</sup> P-value <sup>c</sup>	RD [95%-CI] <sup>b</sup>	
Itching	ITCHES EVEN MORE	0	2 (13.3%)	2 (4.5%)	0.0829 [0.0036, 1.9157]	0.1048 [0.0055, 1.9964]	-0.1349 [-0.3077, 0.0378]	
	ITCHES WORSE	1 (3.4%)	0	1 (2.3%)	1.6154 [0.0603, 43.2473]	1.5714 [0.0696, 35.4581]	0.0337 [-0.0320, 0.0995]	
Overall number of abnormal injection-site reactions		22 (75.9%)	9 (60.0%)	31 (70.5%)	2.0726 [0.5435, 7.9044]	1.2610 [0.7940, 2.0029]	0.1566 [-0.1365, 0.4498]	0.2905

Each subject is counted only once within each symptom. If a subject experiences more than one event within a symptom, only the event with the maximum severity is included in the summary. a: Estimates of RR <1, OR <1, and RD <0 correspond to a benefit for TransCon hGH. b: The 95% CI was calculated for the OR, RD, and RR using the Cochran-Mantel-Haenszel method. c: The p-value given refers to Correlation Statistic with treatment by response. The subgroup interaction p-value is obtained from the logistic model with treatment, subgroup, and treatment\*subgroup as independent variables and adverse events as the dependent variable.

Source: ... \biometrics\hgh\ct-301\adhoc\amnog\_dossier\prog\t-maxsevSYM-inj-pp-sub.sas  
Data Extracted: 03May2019

v9.4 03MAR2023:10:56 Page 4 of 4