Dossier zur Nutzenbewertung gemäß § 35a SGB V

Lonapegsomatropin (Skytrofa®)

Ascendis Pharma Endocrinology GmbH

Separater Anhang 4-H

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

Stand: 14.09.2023

Inhaltsverzeichnis

Table 1.4 Annualized Height Velocity at Week 52 ANCOVA Analysis, subgroup analysis
ITT Population

Age

| Sub Group Treatment | Week 52 | | | TransCon hGH vs. Daily rhGH | | Interaction |
	N[a]/n[b]	Mean (SD)	LS-Mean(SE)[c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	p-value
Age <= 6						
TransCon hGH	42/42	11.34 (1.808)	11.243 (0.4325)	1.257 [0.368, 2.146] 0.0064	0.70 [0.166,1.226]	0.4652
Daily rhGH	22/22	10.10 (1.726)	9.985 (0.4799)			
Age > 6						
TransCon hGH	58/56	10.16 (1.880)	10.228 (0.2600)	0.800 [0.076, 1.525] 0.0308	0.49 [0.045,0.944]	
Daily rhGH	31/30	9.23 (1.891)	9.427 (0.3222)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. Within treatment statistics and between treatment comparison was performed using ANCOVA model including AHV at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS - average SDS of parental height as covariates, treatment and gender as factors. 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.

Table 1.4 Annualized Height Velocity at Week 52 ANCOVA Analysis, subgroup analysis
ITT Population

Gender

Sub Group Treatment	N[a]/n[b]	Week 52 Mean (SD)	LS-Mean(SE)[c]	TransCon hGH vs. Daily rhGH Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
Male						
TransCon hGH	87/85	10.68 (1.907)	10.659 (0.1758)	1.088 [0.490, 1.686] 0.0005	0.61 [0.236,0.979]	0.2995
Daily rhGH	45/44	9.53 (1.887)	9.571 (0.2448)			
Female						
TransCon hGH	13/13	10.56 (2.160)	10.339 (0.4734)	-0.008 [-1.717, 1.701] 0.9922	0.29 [-0.598,1.173]	
Daily rhGH	8/8	9.98 (1.746)	10.347 (0.6154)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. Within treatment statistics and between treatment comparison was performed using ANCOVA model including AHV at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS - average SDS of parental height as covariates, treatment and gender as factors. 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.

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-anco52.sas
Data Extracted: 29Apr2022

Table 1.4 Annualized Height Velocity at Week 52 ANCOVA Analysis, subgroup analysis
ITT Population

Baseline GH-stimulation strata

Sub Group Treatment	Week 52			TransCon hGH vs. Daily rhGH		
	N[a]/n[b]	Mean (SD)	LS-Mean(SE) [c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
<= 5 ng/mL						
TransCon hGH	25/24	12.05 (2.170)	11.955 (0.4592)	1.182 [-0.168, 2.532] 0.0840	0.89 [0.181,1.594]	0.3339
Daily rhGH	13/13	10.25 (1.729)	10.773 (0.6008)			
> 5 ng/mL						
TransCon hGH	75/74	10.22 (1.625)	10.172 (0.2505)	0.801 [0.194, 1.408] 0.0102	0.49 [0.095,0.882]	
Daily rhGH	40/39	9.38 (1.869)	9.371 (0.2923)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. Within treatment statistics and between treatment comparison was performed using ANCOVA model including AHV at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS - average SDS of parental height as covariates, treatment and gender as factors. 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.

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-anco52.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:28 Page 3 of 5

Table 1.4 Annualized Height Velocity at Week 52 ANCOVA Analysis, subgroup analysis
ITT Population

Etiology and extend of GHD

Sub Group Treatment	Week 52			TransCon hGH vs. Daily rhGH		
	N[a]/n[b]	Mean (SD)	LS-Mean(SE)[c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value

Isolated idiopathic

TransCon hGH	83/81	10.56 (1.933)	10.481 (0.2407)	0.946 [0.345, 1.547] 0.0023	0.51 [0.143,0.878]	0.3135
Daily rhGH	47/46	9.57 (1.919)	9.534 (0.2894)			

Isolated organic

TransCon hGH	14/14	11.14 (2.097)	11.414 (0.5172)	2.188 [0.538, 3.837] 0.0133	0.95 [-0.120,2.020]	
Daily rhGH	5/5	9.34 (0.972)	9.227 (0.6638)			

Multiple pituitary hormone deficiencies

TransCon hGH	3/3	11.39 (0.135)	NC (NC)	NC [NC, NC] NC	NC [NC, NC]	
Daily rhGH	1/1	12.03 (NC)	NC (NC)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. Within treatment statistics and between treatment comparison was performed using ANCOVA model including AHV at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS - average SDS of parental height as covariates, treatment and gender as factors. 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.

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-anco52.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:28 Page 4 of 5

Table 1.4 Annualized Height Velocity at Week 52 ANCOVA Analysis, subgroup analysis
ITT Population

Peak stimulated GH concentration at baseline

Sub Group Treatment	N^a/n^b	Week 52 Mean (SD)	LS-Mean(SE) ^{c}	TransCon hGH vs. Daily rhGH Difference in LS Mean ^{c} [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
< 8 ng/mL						
TransCon hGH	71/69	10.79 (2.075)	10.690 (0.2609)	0.770 [0.062, 1.477] 0.0333	0.53 [0.122,0.934]	0.3486
Daily rhGH	38/37	9.73 (1.834)	9.921 (0.3477)			
>= 8 ng/mL						
TransCon hGH	29/29	10.38 (1.528)	11.021 (0.4228)	1.645 [0.624, 2.666] 0.0023	0.67 [0.027,1.305]	
Daily rhGH	15/15	9.26 (1.935)	9.376 (0.3907)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. Within treatment statistics and between treatment comparison was performed using ANCOVA model including AHV at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS - average SDS of parental height as covariates, treatment and gender as factors. 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.

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-anco52.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:28 Page 5 of 5

Table 1.8 Annualized Height Velocity by Visit: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis
ITT Population

Age

Sub Group Treatment		Week 52		TransCon hGH vs. Daily rhGH		
	N[a]/n[b]	Mean (SD)	LS-Mean(SE)[c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
AGE < 6 Years						
TransCon hGH	42/42	11.34 (1.808)	11.24 (0.432)	1.26 [0.368, 2.146] 0.0064	0.70 [0.166,1.226]	0.3773
Daily rhGH	22/22	10.10 (1.726)	9.99 (0.480)			
AGE >= 6 Years						
TransCon hGH	58/58	10.12 (1.863)	10.19 (0.257)	0.72 [0.017, 1.418] 0.0448	0.44 [0.003,0.885]	
Daily rhGH	31/31	9.29 (1.889)	9.48 (0.318)			

NC indicates the calculation was not performed due to the limited sample size in this subgroup. 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 : More than 7 Footnotes

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-ancova-mi-sub.sas
Data Extracted: 29Apr2022

Table 1.8 Annualized Height Velocity by Visit: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis
ITT Population

Gender

Sub Group Treatment		Week 52		TransCon hGH vs. Daily rhGH		
	N^a/n^b	Mean (SD)	LS-Mean(SE) [c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value

Male

| TransCon hGH | 87/87 | 10.64 (1.904) | 10.62 (0.174) | 1.02 [0.433, 1.606] 0.0007 | 0.57 [0.204,0.937] | 0.3453 |
| Daily rhGH | 45/45 | 9.56 (1.880) | 9.60 (0.242) | | | |

Female

| TransCon hGH | 13/13 | 10.56 (2.160) | 10.34 (0.473) | -0.01 [-1.717, 1.701] 0.9922 | 0.29 [-0.598,1.173] | |
| Daily rhGH | 8/8 | 9.98 (1.746) | 10.35 (0.615) | | | |

NC indicates the calculation was not performed due to the limited sample size in this subgroup. 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 : More than 7 Footnotes

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-ancova-mi-sub.sas
Data Extracted: 29Apr2022

Table 1.8 Annualized Height Velocity by Visit: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis
ITT Population

Baseline GH-stimulation strata

Sub Group Treatment	N^a/n^b	Week 52 Mean (SD)	LS-Mean(SE) ^{c}	TransCon hGH vs. Daily rhGH Difference in LS Mean^c [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
<=5 ng/mL						
TransCon hGH	25/25	11.90 (2.249)	11.85 (0.459)	1.05 [-0.232, 2.340] 0.1082	0.79 [0.096,1.485]	0.4060
Daily rhGH	13/13	10.25 (1.729)	10.80 (0.599)			
>5 ng/mL						
TransCon hGH	75/75	10.21 (1.615)	10.16 (0.249)	0.76 [0.165, 1.351] 0.0122	0.46 [0.073,0.850]	
Daily rhGH	40/40	9.42 (1.864)	9.40 (0.290)			

NC indicates the calculation was not performed due to the limited sample size in this subgroup. 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 : More than 7 Footnotes

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-ancova-mi-sub.sas
Data Extracted: 29Apr2022

Table 1.8 Annualized Height Velocity by Visit: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis
ITT Population

Etiology and extend of GHD

Sub Group Treatment	N[a]/n[b]	Week 52 Mean (SD)	Week 52 LS-Mean(SE) [c]	TransCon hGH vs. Daily rhGH Difference in LS Mean[c] [95 %-CI] p-value	TransCon hGH vs. Daily rhGH Hedges'g [95 %-CI]	Interaction p-value
Isolated Idiopathic						
TransCon hGH	83/83	10.52 (1.927)	10.45 (0.241)	0.87 [0.281, 1.463] 0.0038	0.48 [0.114,0.839]	0.3029
Daily rhGH	47/47	9.61 (1.911)	9.58 (0.289)			
Isolated Organic						
TransCon hGH	14/14	11.14 (2.097)	11.41 (0.517)	2.19 [0.538, 3.837] 0.0133	0.95 [-0.120,2.020]	
Daily rhGH	5/5	9.34 (0.972)	9.23 (0.664)			
Multiple Pituitary Hormone Deficiencies						
TransCon hGH	3/3	11.39 (0.135)	NC (NC)	NC [NC, NC] NC	NC [NC, NC]	
Daily rhGH	1/1	12.03 (NC)	NC (NC)			

NC indicates the calculation was not performed due to the limited sample size in this subgroup. 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 : More than 7 Footnotes

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-ancova-mi-sub.sas
Data Extracted: 29Apr2022

Table 1.8 Annualized Height Velocity by Visit: ANCOVA Analysis, Missing Data Imputed with Multiple Imputation, subgroup analysis
ITT Population

Peak stimulated GH concentration at baseline

Sub Group Treatment	Nᵃ/nᵇ	Week 52 Mean (SD)	LS-Mean(SE) ᶜ	TransCon hGH vs. Daily rhGH Difference in LS Meanᶜ [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
< 8 ng/mL						
TransCon hGH	71/71	10.74 (2.070)	10.65 (0.259)	0.69 [0.005, 1.378] 0.0483	0.49 [0.088,0.886]	0.2764
Daily rhGH	38/38	9.77 (1.822)	9.96 (0.344)			
>= 8 ng/mL						
TransCon hGH	29/29	10.38 (1.528)	11.02 (0.423)	1.65 [0.624, 2.666] 0.0023	0.67 [0.027,1.305]	
Daily rhGH	15/15	9.26 (1.935)	9.38 (0.391)			

NC indicates the calculation was not performed due to the limited sample size in this subgroup. 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 : More than 7 Footnotes

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-ahv-ancova-mi-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:24 Page 5 of 5

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

Age

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Daily rhGH		Interaction p-value
	N[a]/n[b]	Mean (SD)	N[a]/n[b]	Mean (SD)	LS-Mean(SE)[c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	
Age <= 6								
TransCon hGH	42/42	-2.66 (0.622)	42/42	1.21 (0.400)	1.21 (0.093)	0.27 [0.079,0.469] 0.0067	0.73 [0.199,1.262]	0.0449
Daily rhGH	22/22	-2.50 (0.480)	22/22	0.92 (0.368)	0.94 (0.105)			
Age > 6								
TransCon hGH	58/58	-2.62 (0.573)	58/56	0.83 (0.386)	0.84 (0.046)	0.10 [-0.032,0.231] 0.1371	0.35 [-0.098,0.795]	
Daily rhGH	31/31	-2.82 (0.692)	31/30	0.70 (0.359)	0.74 (0.059)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. The ANCOVA model include change from baseline in height SDS at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS as covariates, treatment and gender as factors. 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.

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-hgsd-ancova-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:23 Page 1 of 5

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

Gender

| Sub Group Treatment | Baseline | | Week 52 | | | TransCon hGH vs. Daily rhGH | | Interaction |
	N^a/n^b	Mean (SD)	N^a/n^b	Mean (SD)	LS-Mean(SE)[c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	p-value
Male								
TransCon hGH	87/87	-2.63 (0.613)	87/85	0.99 (0.443)	0.99 (0.037)	0.21 [0.084,0.335] 0.0013	0.50 [0.130,0.868]	0.6564
Daily rhGH	45/45	-2.62 (0.595)	45/44	0.78 (0.392)	0.78 (0.052)			
Female								
TransCon hGH	13/13	-2.68 (0.436)	13/13	0.97 (0.365)	0.93 (0.081)	0.01 [-0.306,0.327] 0.9466	0.34 [-0.548,1.226]	
Daily rhGH	8/8	-3.05 (0.735)	8/8	0.86 (0.281)	0.92 (0.109)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. The ANCOVA model include change from baseline in height SDS at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS as covariates, treatment and gender as factors. 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.

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-hgsd-ancova-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:23 Page 2 of 5

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

Baseline GH-stimulation strata

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Daily rhGH		
	N^a/n^b	Mean (SD)	N^a/n^b	Mean (SD)	LS-Mean(SE)^c	Difference in LS Mean^c [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
<= 5 ng/mL								
TransCon hGH	25/25	-2.97 (0.896)	25/24	1.19 (0.500)	1.22 (0.090)	0.29 [0.029,0.557] 0.0309	0.62 [-0.069,1.312]	0.6365
Daily rhGH	13/13	-3.03 (0.953)	13/13	0.91 (0.379)	0.93 (0.122)			
> 5 ng/mL								
TransCon hGH	75/75	-2.53 (0.397)	75/74	0.92 (0.389)	0.94 (0.049)	0.16 [0.036,0.275] 0.0113	0.44 [0.052,0.837]	
Daily rhGH	40/40	-2.58 (0.444)	40/39	0.75 (0.372)	0.78 (0.057)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. The ANCOVA model include change from baseline in height SDS at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS as covariates, treatment and gender as factors. 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.

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-hgsd-ancova-sub.sas
Data Extracted: 29Apr2022

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

Etiology and extend of GHD

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Daily rhGH		
	N^a/n^b	Mean (SD)	N^a/n^b	Mean (SD)	LS-Mean(SE)[c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
Isolated idiopathic								
TransCon hGH	83/83	-2.61 (0.565)	83/81	0.98 (0.448)	0.98 (0.048)	0.19 [0.068,0.304] 0.0023	0.46 [0.090,0.822]	0.0243
Daily rhGH	47/47	-2.63 (0.566)	47/46	0.79 (0.375)	0.79 (0.057)			
Isolated organic								
TransCon hGH	14/14	-2.65 (0.566)	14/14	1.10 (0.321)	1.23 (0.100)	0.47 [0.124,0.822] 0.0118	1.16 [0.068,2.255]	
Daily rhGH	5/5	-2.88 (0.761)	5/5	0.72 (0.355)	0.75 (0.133)			
Multiple pituitary hormone deficiencies								
TransCon hGH	3/3	-3.26 (1.236)	3/3	0.73 (0.391)	NC (NC)	NC [NC, NC] NC	NC [NC, NC]	
Daily rhGH	1/1	-4.46 (NC)	1/1	1.38 (NC)	NC (NC)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. The ANCOVA model include change from baseline in height SDS at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS as covariates, treatment and gender as factors. 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.

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

Peak stimulated GH concentration at baseline

Sub Group Treatment	Baseline		Week 52			TransCon hGH vs. Daily rhGH		
	N[a]/n[b]	Mean (SD)	N[a]/n[b]	Mean (SD)	LS-Mean(SE)[c]	Difference in LS Mean[c] [95 %-CI] p-value	Hedges'g [95 %-CI]	Interaction p-value
< 8 ng/mL								
TransCon hGH	71/71	-2.69 (0.640)	71/69	1.02 (0.436)	1.02 (0.053)	0.18 [0.032,0.319] 0.0173	0.49 [0.085,0.895]	0.3158
Daily rhGH	38/38	-2.75 (0.696)	38/37	0.82 (0.371)	0.84 (0.071)			
>= 8 ng/mL								
TransCon hGH	29/29	-2.51 (0.432)	29/29	0.92 (0.423)	1.08 (0.088)	0.32 [0.107,0.528] 0.0040	0.46 [-0.175,1.087]	
Daily rhGH	15/15	-2.53 (0.386)	15/15	0.73 (0.394)	0.76 (0.079)			

Absolute data. NC indicates the calculation was not performed due to the limited sample size in this subgroup. The ANCOVA model include change from baseline in height SDS at each visit as response variable, baseline age, peak GH levels (log transformed), baseline height SDS as covariates, treatment and gender as factors. 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.

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-hgsd-ancova-sub.sas
Data Extracted: 29Apr2022

Table 1.12 Summary of Adverse Events, subgroup analysis by age
Safety Population

Age: < 6 years

Number of Subjects with	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH[a]			Subgroup Interaction p-value
				OR [95 %-CI][b]	RR [95 %-CI][b] p-value[c]	RD [95 %-CI][b]	
Treatment emergent adverse events (TEAE)	41 (97.6%)	21 (95.5%)	62 (96.9%)	1.9524 [0.1162, 32.7963]	1.0227 [0.9229, 1.1333] 0.6391	0.0216 [-0.0769, 0.1201]	0.7131
TEAEs related to study drug	21 (50.0%)	4 (18.2%)	25 (39.1%)				
Serious AEs	2 (4.8%)	2 (9.1%)	4 (6.3%)	0.5000 [0.0655, 3.8152]	0.5238 [0.0791, 3.4703] 0.5002	-0.0433 [-0.1796, 0.0930]	0.9728
Serious AEs related to study drug	1 (2.4%)	0	1 (1.6%)				
TEAEs leading to any action on study drug	6 (14.3%)	6 (27.3%)	12 (18.8%)				
TEAEs leading to discontinuation of study drug	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022

v9.4 31MAY2023:11:09 Page 1 of 2

Table 1.12 Summary of Adverse Events, subgroup analysis by age
Safety Population

Age: >= 6 years

| | | | | Lonapegsomatropin vs. Daily rhGH[a] | | |
| | | | | OR
[95 %-CI][b] | RR
[95 %-CI][b]
p-value[c] | RD
[95 %-CI][b] |
Number of Subjects with	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)			
Treatment emergent adverse events (TEAE)	57 (98.3%)	29 (93.5%)	86 (96.6%)	3.9310 [0.3420, 45.1790]	1.0505 [0.9520, 1.1593] 0.2417	0.0473 [-0.0455, 0.1400]
TEAEs related to study drug	27 (46.6%)	15 (48.4%)	42 (47.2%)			
Serious AEs	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	13 (22.4%)	9 (29.0%)	22 (24.7%)			
TEAEs leading to discontinuation of study drug	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022   v9.4 31MAY2023:11:09 Page 2 of 2

Table 1.13 Summary of Adverse Events, subgroup analysis by gender
Safety Population

Male

| Number of Subjects with | TransCon hGH (N=87) | Daily rhGH (N=45) | Total (N=132) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Treatment emergent adverse events (TEAE)	87 (100.0%)	43 (95.6%)	130 (98.5%)	6.0073 [0.6070, 59.4557]	1.0459 [0.9824, 1.1135] 0.0492	0.0445 [-0.0158, 0.1047]	0.9722
TEAEs related to study drug	44 (50.6%)	15 (33.3%)	59 (44.7%)				
Serious AEs	4 (4.6%)	2 (4.4%)	6 (4.5%)	1.0326 [0.1812, 5.8857]	1.0309 [0.1977, 5.3745] 0.9713	0.0014 [-0.0731, 0.0758]	0.9999
Serious AEs related to study drug	1 (1.1%)	0	1 (0.8%)				
TEAEs leading to any action on study drug	17 (19.5%)	12 (26.7%)	29 (22.0%)				
TEAEs leading to discontinuation of study drug	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022

Table 1.13 Summary of Adverse Events, subgroup analysis by gender
Safety Population

Female

Number of Subjects with	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Treatment emergent adverse events (TEAE)	11 (84.6%)	7 (87.5%)	18 (85.7%)	0.7895 [0.0655, 9.5205]	0.9653 [0.6696, 1.3916] 0.8554	-0.0303 [-0.3427, 0.2821]
TEAEs related to study drug	4 (30.8%)	4 (50.0%)	8 (38.1%)			
Serious AEs	0	0	0			
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	2 (15.4%)	3 (37.5%)	5 (23.8%)			
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022
v9.4 31MAY2023:11:09 Page 2 of 2

Table 1.14 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Treatment emergent adverse events (TEAE)	25 (100.0%)	13 (100.0%)	38 (100.0%)				0.9981
TEAEs related to study drug	12 (48.0%)	7 (53.8%)	19 (50.0%)				
Serious AEs	0	1 (7.7%)	1 (2.6%)	0.1373 [0.0044, 4.2556]	0.1852 [0.0091, 3.7499] 0.1573	-0.0780 [-0.2236, 0.0677]	0.9738
Serious AEs related to study drug	0	0	0				
TEAEs leading to any action on study drug	4 (16.0%)	6 (46.2%)	10 (26.3%)				
TEAEs leading to discontinuation of study drug	0	0	0				0.9739
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022

v9.4 31MAY2023:11:09 Page 1 of 2

Table 1.14 Summary of Adverse Events, subgroup analysis by baseline GH-stimulation strata
Safety Population

Baseline GH-stimulation strata: > 5 ng/mL

| | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
Number of Subjects with	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Treatment emergent adverse events (TEAE)	73 (97.3%)	37 (92.5%)	110 (95.7%)	2.9555 [0.4736, 18.4454]	1.0522 [0.9560, 1.1581] 0.2303	0.0483 [-0.0411, 0.1377]
TEAEs related to study drug	36 (48.0%)	12 (30.0%)	48 (41.7%)			
Serious AEs	4 (5.3%)	1 (2.5%)	5 (4.3%)	2.1974 [0.2356, 20.4949]	2.1270 [0.2476, 18.2752] 0.4822	0.0282 [-0.0418, 0.0983]
Serious AEs related to study drug	1 (1.3%)	0	1 (0.9%)			
TEAEs leading to any action on study drug	15 (20.0%)	9 (22.5%)	24 (20.9%)			
TEAEs leading to discontinuation of study drug	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022
v9.4 31MAY2023:11:09 Page 2 of 2

Table 1.15 Summary of Adverse Events, subgroup analysis by etiology and extend of GHD
Safety Population

Isolated idiopathic

Number of Subjects with	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Treatment emergent adverse events (TEAE)	81 (97.6%)	44 (93.6%)	125 (96.2%)	2.7589 [0.4433, 17.1715] 0.2629	1.0423 [0.9605, 1.1311]	0.0396 [-0.0376, 0.1168]	1.0000
TEAEs related to study drug	37 (44.6%)	15 (31.9%)	52 (40.0%)				
Serious AEs	4 (4.8%)	2 (4.3%)	6 (4.6%)	1.1166 [0.1970, 6.3285] 0.9009	1.1103 [0.2158, 5.7123]	0.0048 [-0.0692, 0.0787]	1.0000
Serious AEs related to study drug	1 (1.2%)	0	1 (0.8%)				
TEAEs leading to any action on study drug	17 (20.5%)	14 (29.8%)	31 (23.8%)				
TEAEs leading to discontinuation of study drug	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886] 0.2884	1.7211 [0.1841, 16.0899]	0.0240 [-0.0089, 0.0570]	0.9993
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022

v9.4 31MAY2023:11:09 Page 1 of 3

Table 1.15 Summary of Adverse Events, subgroup analysis by etiology and extend of GHD
Safety Population

Isolated organic (determined by abnormal MRI)

| | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
Number of Subjects with	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Treatment emergent adverse events (TEAE)	14 (100.0%)	5 (100.0%)	19 (100.0%)			
TEAEs related to study drug	9 (64.3%)	3 (60.0%)	12 (63.2%)			
Serious AEs	0	0	0			
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	1 (7.1%)	0	1 (5.3%)			
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022

Table 1.15 Summary of Adverse Events, subgroup analysis by etiology and extend of GHD
Safety Population

Multiple pituitary hormone deficiencies

Number of Subjects with	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Treatment emergent adverse events (TEAE)	3 (100.0%)	1 (100.0%)	4 (100.0%)			
TEAEs related to study drug	2 (66.7%)	1 (100.0%)	3 (75.0%)			
Serious AEs	0	0	0			
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	1 (33.3%)	1 (100.0%)	2 (50.0%)			
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022

Table 1.16 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Treatment emergent adverse events (TEAE)	69 (97.2%)	36 (94.7%)	105 (96.3%)	1.9327 [0.2605, 14.3364]	1.0261 [0.9427, 1.1168] 0.5167	0.0247 [-0.0560, 0.1054]	0.9768
TEAEs related to study drug	33 (46.5%)	14 (36.8%)	47 (43.1%)				
Serious AEs	4 (5.6%)	2 (5.3%)	6 (5.5%)	1.0588 [0.1826, 6.1381]	1.0545 [0.2075, 5.3595] 0.9495	0.0029 [-0.0855, 0.0913]	0.9999
Serious AEs related to study drug	1 (1.4%)	0	1 (0.9%)				
TEAEs leading to any action on study drug	14 (19.7%)	12 (31.6%)	26 (23.9%)				
TEAEs leading to discontinuation of study drug	2 (2.8%)	0	2 (1.8%)	1.6656 [0.1672, 16.5962]	1.6364 [0.1763, 15.1865] 0.3023	0.0281 [-0.0104, 0.0665]	0.9815
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022

v9.4 31MAY2023:11:09 Page 1 of 2

Table 1.16 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=29)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Treatment emergent adverse events (TEAE)	29 (100.0%)	14 (93.3%)	43 (97.7%)	6.6923 [0.2391, 187.2785]	1.1667 [0.8622, 1.5787] 0.1573	0.0674 [-0.0594, 0.1943]
TEAEs related to study drug	15 (51.7%)	5 (33.3%)	20 (45.5%)			
Serious AEs	0	0	0			
Serious AEs related to study drug	0	0	0			
TEAEs leading to any action on study drug	5 (17.2%)	3 (20.0%)	8 (18.2%)			
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-cn-visen\adhoc\amnog_dossier\prog\t-ae-sub.sas
Data Extracted: 29Apr2022

v9.4 31MAY2023:11:09 Page 2 of 2

Table 1.24 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE: >=10%
in any treatment group
Safety Population

Age: < 6 years

System Organ Class	Preferred Term	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Any adverse event		41 (97.6%)	21 (95.5%)	62 (96.9%)	1.3016 [0.2016, 8.4021]	1.0206 [0.8790, 1.1849] 0.7829	0.0188 [-0.1184, 0.1559]	0.3182
Infections and infestations		32 (76.2%)	19 (86.4%)	51 (79.7%)	0.5053 [0.1234, 2.0686]	0.8822 [0.6961, 1.1181] 0.3405	-0.1017 [-0.2945, 0.0910]	0.5164
	Upper respiratory tract infection	23 (54.8%)	19 (86.4%)	42 (65.6%)	0.1911 [0.0490, 0.7453]	0.6341 [0.4599, 0.8742] 0.0121	-0.3160 [-0.5239, -0.1081]	0.0435
	Bronchitis	8 (19.0%)	2 (9.1%)	10 (15.6%)	2.3529 [0.4542, 12.1904]	2.0952 [0.4861, 9.0320] 0.3012	0.0996 [-0.0694, 0.2685]	0.9811
Investigations		24 (57.1%)	9 (40.9%)	33 (51.6%)	1.9259 [0.6761, 5.4861]	1.3968 [0.7928, 2.4611] 0.2207	0.1623 [-0.0918, 0.4165]	0.0380
	Insulin-like growth factor increased	17 (40.5%)	1 (4.5%)	18 (28.1%)	14.2800 [1.7512, 116.4467]	8.9048 [1.2673, 62.5704] 0.0026	0.3593 [0.1872, 0.5314]	0.3202
	Blood glucose increased	4 (9.5%)	4 (18.2%)	8 (12.5%)	0.4737 [0.1062, 2.1125]	0.5238 [0.1447, 1.8959] 0.3237	-0.0866 [-0.2706, 0.0974]	0.7385

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 1 of 6

Table 1.24 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE: >=10%
in any treatment group
Safety Population

Age: < 6 years

System Organ Class	Preferred Term	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
	Blood alkaline phosphatase increased	2 (4.8%)	3 (13.6%)	5 (7.8%)	0.3167 [0.0488, 2.0560]	0.3492 [0.0630, 1.9370] 0.2125	-0.0887 [-0.2459, 0.0685]	0.7678
Respiratory, thoracic and mediastinal disorders		18 (42.9%)	5 (22.7%)	23 (35.9%)	2.5500 [0.7918, 8.2120]	1.8857 [0.8093, 4.3941] 0.1137	0.2013 [-0.0291, 0.4317]	0.2339
	Cough	15 (35.7%)	3 (13.6%)	18 (28.1%)	3.5185 [0.8927, 13.8675]	2.6190 [0.8484, 8.0847] 0.0641	0.2208 [0.0169, 0.4246]	0.2964
General disorders and administration site conditions		9 (21.4%)	4 (18.2%)	13 (20.3%)	1.4063 [0.3850, 5.1361]	1.3095 [0.4636, 3.6993] 0.6078	0.0563 [-0.1500, 0.2626]	0.2842
	Pyrexia	7 (16.7%)	3 (13.6%)	10 (15.6%)	1.4902 [0.3528, 6.2945]	1.3968 [0.4113, 4.7433] 0.5887	0.0541 [-0.1321, 0.2403]	0.6411
Gastrointestinal disorders		5 (11.9%)	6 (27.3%)	11 (17.2%)	0.3604 [0.0959, 1.3541]	0.4365 [0.1499, 1.2711] 0.1246	-0.1537 [-0.3640, 0.0566]	0.2077

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 2 of 6

Table 1.24 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE: >=10%
in any treatment group
Safety Population

Age: < 6 years

					Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders		7 (16.7%)	1 (4.5%)	8 (12.5%)	4.2000 [0.4824, 36.5650]	3.6667 [0.4812, 27.9408] 0.1671	0.1212 [-0.0212, 0.2636]	0.0441
Skin and subcutaneous tissue disorders		5 (11.9%)	0	5 (7.8%)	6.6000 [0.3483, 125.0769]	5.8837 [0.3402, 101.7613] 0.0945	0.1190 [0.0211, 0.2170]	0.9689
Eye disorders		0	0	0				0.2466
Nervous system disorders		0	0	0				0.9803
	Headache	0	0	0				0.9979

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 3 of 6

Table 1.24 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE: >=10%
in any treatment group
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Any adverse event		57 (98.3%)	29 (93.5%)	86 (96.6%)	5.8966 [0.5871, 59.2207]	1.0844 [0.9651, 1.2185] 0.0936	0.0765 [-0.0299, 0.1829]
Investigations		26 (44.8%)	20 (64.5%)	46 (51.7%)	0.4469 [0.1818, 1.0986]	0.6948 [0.4719, 1.0230] 0.0783	-0.1969 [-0.4084, 0.0147]
	Blood glucose increased	13 (22.4%)	14 (45.2%)	27 (30.3%)	0.3508 [0.1372, 0.8969]	0.4963 [0.2680, 0.9191] 0.0270	-0.2275 [-0.4329, -0.0220]
	Insulin-like growth factor increased	12 (20.7%)	2 (6.5%)	14 (15.7%)	3.7826 [0.7890, 18.1349]	3.2069 [0.7659, 13.4278] 0.0805	0.1424 [0.0069, 0.2778]
	Blood alkaline phosphatase increased	0	0	0			
Infections and infestations		28 (48.3%)	16 (51.6%)	44 (49.4%)	0.8750 [0.3656, 2.0940]	0.9353 [0.6069, 1.4416] 0.7655	-0.0334 [-0.2513, 0.1845]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

Table 1.24 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE: >=10%
in any treatment group
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Upper respiratory tract infection	21 (36.2%)	11 (35.5%)	32 (36.0%)	1.0319 [0.4154, 2.5636]	1.0204 [0.5686, 1.8312] 0.9463	0.0072 [-0.2017, 0.2162]
	Bronchitis	0	0	0			
Respiratory, thoracic and mediastinal disorders		15 (25.9%)	8 (25.8%)	23 (25.8%)	1.0029 [0.3703, 2.7161]	1.0022 [0.4786, 2.0984] 0.9955	0.0006 [-0.1903, 0.1914]
	Cough	12 (20.7%)	5 (16.1%)	17 (19.1%)	1.3565 [0.4301, 4.2789]	1.2828 [0.4972, 3.3094] 0.6041	0.0456 [-0.1206, 0.2118]
General disorders and administration site conditions		11 (19.0%)	9 (29.0%)	20 (22.5%)	0.5721 [0.2071, 1.5803]	0.6533 [0.3038, 1.4045] 0.2811	-0.1007 [-0.2896, 0.0883]
	Pyrexia	9 (15.5%)	5 (16.1%)	14 (15.7%)	0.9551 [0.2899, 3.1463]	0.9621 [0.3530, 2.6217] 0.9401	-0.0061 [-0.1656, 0.1534]
Gastrointestinal disorders		12 (20.7%)	6 (19.4%)	18 (20.2%)	1.0870 [0.3639, 3.2469]	1.0690 [0.4444, 2.5710] 0.8819	0.0133 [-0.1605, 0.1872]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

Table 1.24 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by age, AE: >=10%
in any treatment group
Safety Population

Age: >= 6 years

System Organ Class	Preferred Term	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders		5 (8.6%)	7 (22.6%)	12 (13.5%)	0.3235 [0.0931, 1.1231]	0.3818 [0.1321, 1.1037] 0.0677	-0.1396 [-0.3036, 0.0244]
Eye disorders		8 (13.8%)	2 (6.5%)	10 (11.2%)	2.3200 [0.4611, 11.6719]	2.1379 [0.4833, 9.4565] 0.2988	0.0734 [-0.0505, 0.1973]
Nervous system disorders		2 (3.4%)	5 (16.1%)	7 (7.9%)	0.1857 [0.0338, 1.0212]	0.2138 [0.0440, 1.0388] 0.0353	-0.1268 [-0.2645, 0.0109]
	Headache	0	4 (12.9%)	4 (4.5%)	0.0522 [0.0027, 1.0046]	0.0603 [0.0033, 1.0842] 0.0054	-0.1290 [-0.2470, -0.0110]
Skin and subcutaneous tissue disorders		0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Male

| System Organ Class | Preferred Term | TransCon hGH (N=87) | Daily rhGH (N=45) | Total (N=132) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Any adverse event		87 (100.0%)	43 (95.6%)	130 (98.5%)	4.1693 [0.7169, 24.2476]	1.0690 [0.9747, 1.1726] 0.0886	0.0632 [-0.0221, 0.1484]	0.3017
Infections and infestations		54 (62.1%)	29 (64.4%)	83 (62.9%)	0.8870 [0.4019, 1.9576]	0.9614 [0.7435, 1.2431] 0.7692	-0.0249 [-0.1885, 0.1387]	0.2777
	Upper respiratory tract infection	39 (44.8%)	25 (55.6%)	64 (48.5%)	0.6207 [0.2902, 1.3275]	0.8052 [0.5768, 1.1239] 0.2212	-0.1084 [-0.2793, 0.0625]	0.5813
	Conjunctivitis	0	0	0				0.9470
	Gastroenteritis	0	0	0				0.9746
	Nasopharyngitis	0	0	0				0.9742
	Pharyngitis	0	0	0				0.9746
	Respiratory tract infection	0	0	0				0.9674
	Urinary tract infection	0	0	0				0.9773
Investigations		47 (54.0%)	25 (55.6%)	72 (54.5%)	0.9411 [0.4607, 1.9226]	0.9722 [0.6990, 1.3523] 0.8670	-0.0154 [-0.1967, 0.1659]	0.2695
	Blood glucose increased	17 (19.5%)	14 (31.1%)	31 (23.5%)	0.5240 [0.2248, 1.2213]	0.6300 [0.3478, 1.1411] 0.1336	-0.1150 [-0.2705, 0.0404]	0.9733

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Male

					Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
	Insulin-like growth factor increased	26 (29.9%)	2 (4.4%)	28 (21.2%)	9.2969 [2.1027, 41.1054]	6.7080 [1.6692, 26.9573] 0.0006	0.2538 [0.1406, 0.3669]	0.3155
	Blood glucose abnormal	0	0	0				0.9746
	Cortisol decreased	0	0	0				0.9726
	Liver function test abnormal	0	0	0				0.9773
Respiratory, thoracic and mediastinal disorders		29 (33.3%)	13 (28.9%)	42 (31.8%)	1.2250 [0.5628, 2.6661]	1.1526 [0.6645, 1.9993] 0.6071	0.0441 [-0.1225, 0.2107]	0.9660
	Cough	23 (26.4%)	8 (17.8%)	31 (23.5%)	1.6486 [0.6744, 4.0301]	1.4852 [0.7199, 3.0641] 0.2685	0.0862 [-0.0598, 0.2323]	0.9696
General disorders and administration site conditions		19 (21.8%)	11 (24.4%)	30 (22.7%)	0.9229 [0.3978, 2.1411]	0.9403 [0.4940, 1.7901] 0.8526	-0.0146 [-0.1685, 0.1394]	0.3479
	Pyrexia	15 (17.2%)	8 (17.8%)	23 (17.4%)	1.0419 [0.4087, 2.6560]	1.0343 [0.4788, 2.2344] 0.9319	0.0061 [-0.1323, 0.1445]	0.9756

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 2 of 9

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Male

					Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
	Injection site swelling	0	0	0				0.9773
	Pain	0	0	0				0.9773
Gastrointestinal disorders		14 (16.1%)	11 (24.4%)	25 (18.9%)	0.5937 [0.2442, 1.4430]	0.6589 [0.3262, 1.3307] 0.2496	-0.0834 [-0.2309, 0.0641]	0.3433
	Diarrhoea	5 (5.7%)	5 (11.1%)	10 (7.6%)	0.4880 [0.1336, 1.7826]	0.5166 [0.1574, 1.6957] 0.2725	-0.0537 [-0.1578, 0.0504]	0.9712
	Abdominal pain	0	0	0				0.9990
Metabolism and nutrition disorders		12 (13.8%)	8 (17.8%)	20 (15.2%)	0.7474 [0.2858, 1.9548]	0.7761 [0.3370, 1.7876] 0.5489	-0.0397 [-0.1749, 0.0954]	0.9992
Eye disorders		10 (11.5%)	3 (6.7%)	13 (9.8%)	1.8367 [0.4769, 7.0731]	1.7295 [0.5042, 5.9324] 0.3731	0.0486 [-0.0499, 0.1471]	0.9725
	Vernal keratoconjunctivitis	0	0	0				0.9773
Endocrine disorders		0	0	0				0.9572
	Precocious puberty	0	0	0				0.9773

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 3 of 9

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Male

| System Organ Class | Preferred Term | TransCon hGH (N=87) | Daily rhGH (N=45) | Total (N=132) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Nervous system disorders		0	0	0				0.9268
	Dizziness	0	0	0				0.9770
	Headache	0	0	0				0.9971
Skin and subcutaneous tissue disorders		0	0	0				0.9704
	Urticaria	0	0	0				0.9938

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 4 of 9

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Female

System Organ Class	Preferred Term	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Any adverse event		11 (84.6%)	7 (87.5%)	18 (85.7%)	0.7895 [0.0655, 9.5205]	0.9653 [0.6696, 1.3916] 0.8554	-0.0303 [-0.3427, 0.2821]
Infections and infestations		6 (46.2%)	6 (75.0%)	12 (57.1%)	0.2632 [0.0342, 2.0229]	0.6216 [0.3138, 1.2313] 0.2087	-0.2828 [-0.6729, 0.1073]
	Upper respiratory tract infection	5 (38.5%)	5 (62.5%)	10 (47.6%)	0.3285 [0.0447, 2.4127]	0.6260 [0.2793, 1.4031] 0.2892	-0.2323 [-0.6297, 0.1650]
	Conjunctivitis	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
	Gastroenteritis	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
	Nasopharyngitis	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
	Pharyngitis	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
	Respiratory tract infection	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Female

System Organ Class	Preferred Term	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Urinary tract infection	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
Investigations		3 (23.1%)	4 (50.0%)	7 (33.3%)	0.2143 [0.0245, 1.8774]	0.4500 [0.1494, 1.3558] 0.1658	-0.2778 [-0.6553, 0.0998]
	Blood glucose increased	0	4 (50.0%)	4 (19.0%)	0.0265 [0.0010, 0.6694]	0.0707 [0.0045, 1.1214] 0.0039	-0.5051 [-0.8498, -0.1603]
	Insulin-like growth factor increased	3 (23.1%)	1 (12.5%)	4 (19.0%)	2.1429 [0.1694, 27.1035]	1.8000 [0.2378, 13.6267] 0.5637	0.1010 [-0.2120, 0.4140]
	Cortisol decreased	1 (7.7%)	1 (12.5%)	2 (9.5%)	0.5556 [0.0282, 10.9333]	0.6000 [0.0454, 7.9215] 0.7055	-0.0505 [-0.3175, 0.2165]
	Blood glucose abnormal	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
	Liver function test abnormal	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
Gastrointestinal disorders		3 (23.1%)	1 (12.5%)	4 (19.0%)	1.8750 [0.1891, 18.5933]	1.8750 [0.1849, 19.0177] 0.5689	0.1061 [-0.2466, 0.4588]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 6 of 9

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Female

System Organ Class	Preferred Term	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Abdominal pain	1 (7.7%)	1 (12.5%)	2 (9.5%)	0.6250 [0.0395, 9.8915]	0.6250 [0.0363, 10.7605] 0.7439	-0.0455 [-0.3266, 0.2357]
	Diarrhoea	0	0	0			
Nervous system disorders		1 (7.7%)	3 (37.5%)	4 (19.0%)	0.1449 [0.0123, 1.7047]	0.2027 [0.0241, 1.7030] 0.1095	-0.2980 [-0.6662, 0.0702]
	Dizziness	1 (7.7%)	1 (12.5%)	2 (9.5%)	0.5556 [0.0282, 10.9333]	0.6000 [0.0454, 7.9215] 0.7055	-0.0505 [-0.3175, 0.2165]
	Headache	0	2 (25.0%)	2 (9.5%)	0.1596 [0.0131, 1.9385]	0.2318 [0.0291, 1.8483] 0.0753	-0.2475 [-0.5471, 0.0521]
Respiratory, thoracic and mediastinal disorders		4 (30.8%)	0	4 (19.0%)	4.4943 [0.4152, 48.6502]	3.1741 [0.4327, 23.2846] 0.0980	0.3081 [0.0571, 0.5591]
	Cough	4 (30.8%)	0	4 (19.0%)	4.4943 [0.4152, 48.6502]	3.1741 [0.4327, 23.2846] 0.0980	0.3081 [0.0571, 0.5591]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 7 of 9

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Female

System Organ Class	Preferred Term	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH ᵃ		
					OR [95 %-CI] ᵇ	RR [95 %-CI] ᵇ p-valueᶜ	RD [95 %-CI] ᵇ
General disorders and administration site conditions		1 (7.7%)	2 (25.0%)	3 (14.3%)	0.2222 [0.0153, 3.2212]	0.3000 [0.0340, 2.6450] 0.2623	-0.1768 [-0.5029, 0.1493]
	Injection site swelling	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
	Pain	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
	Pyrexia	0	0	0			
Skin and subcutaneous tissue disorders		3 (23.1%)	0	3 (14.3%)	3.4405 [0.3098, 38.2094]	2.6666 [0.3538, 20.0978] 0.1624	0.2323 [0.0029, 0.4617]
	Urticaria	2 (15.4%)	0	2 (9.5%)	2.4420 [0.2068, 28.8365]	2.0858 [0.2615, 16.6347] 0.2605	0.1566 [-0.0407, 0.3538]
Endocrine disorders		0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
	Precocious puberty	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 8 of 9

Table 1.25 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by gender, AE:
>=10% in any treatment group
Safety Population

Female

| | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
System Organ Class	Preferred Term	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Eye disorders		0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
	Vernal keratoconjunctivitis	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
Metabolism and nutrition disorders		0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

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

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

System Organ Class	Preferred Term	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Any adverse event		25 (100.0%)	13 (100.0%)	38 (100.0%)	5.5939 [0.5249, 59.6162]	1.1352 [0.9417, 1.3684] 0.0693	0.1328 [-0.0390, 0.3046]	0.9706
Infections and infestations		11 (44.0%)	9 (69.2%)	20 (52.6%)	0.2586 [0.0510, 1.3119]	0.6285 [0.3759, 1.0510] 0.1052	-0.2579 [-0.5420, 0.0262]	0.1998
	Upper respiratory tract infection	9 (36.0%)	8 (61.5%)	17 (44.7%)	0.2045 [0.0350, 1.1938]	0.5752 [0.3262, 1.0145] 0.0769	-0.2624 [-0.5342, 0.0095]	0.3789
	Pharyngitis	0	2 (15.4%)	2 (5.3%)	0.1495 [0.0138, 1.6173]	0.1852 [0.0213, 1.6070] 0.0486	-0.1544 [-0.3508, 0.0419]	0.9509
	Bronchitis	0	0	0				0.9800
	Tonsillitis	0	0	0				0.9768
Investigations		12 (48.0%)	8 (61.5%)	20 (52.6%)	0.5893 [0.1560, 2.2257]	0.7756 [0.4194, 1.4344] 0.4230	-0.1379 [-0.4766, 0.2007]	0.5510
	Blood glucose increased	4 (16.0%)	6 (46.2%)	10 (26.3%)	0.2172 [0.0464, 1.0167]	0.3485 [0.1201, 1.0113] 0.0497	-0.2999 [-0.6044, 0.0047]	0.3833
	Insulin-like growth factor increased	7 (28.0%)	1 (7.7%)	8 (21.1%)	4.1905 [0.5089, 34.5076]	3.6275 [0.4720, 27.8770] 0.1527	0.2009 [-0.0340, 0.4358]	0.7014

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 1 of 6

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

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

System Organ Class	Preferred Term	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
	Blood alkaline phosphatase increased	0	0	0				0.9694
Gastrointestinal disorders		8 (32.0%)	3 (23.1%)	11 (28.9%)	1.5714 [0.3380, 7.3051]	1.3896 [0.4421, 4.3674] 0.5716	0.0900 [-0.2037, 0.3836]	0.2004
	Diarrhoea	3 (12.0%)	1 (7.7%)	4 (10.5%)	1.6444 [0.1530, 17.6779]	1.5686 [0.1786, 13.7793] 0.6862	0.0435 [-0.1493, 0.2363]	0.3078
Respiratory, thoracic and mediastinal disorders		6 (24.0%)	3 (23.1%)	9 (23.7%)	1.0596 [0.2188, 5.1320]	1.0455 [0.3108, 3.5163] 0.9436	0.0105 [-0.2742, 0.2952]	0.6073
	Cough	5 (20.0%)	1 (7.7%)	6 (15.8%)	3.1282 [0.3133, 31.2386]	2.6275 [0.3465, 19.9223] 0.3258	0.1244 [-0.0861, 0.3350]	0.7332
	Rhinorrhoea	0	0	0				0.9688
General disorders and administration site conditions		4 (16.0%)	2 (15.4%)	6 (15.8%)	1.0769 [0.1563, 7.4204]	1.0588 [0.2380, 4.7110] 0.9412	0.0090 [-0.2236, 0.2416]	0.7707
	Pyrexia	4 (16.0%)	0	4 (10.5%)	6.3333 [0.3038, 132.0494]	5.0000 [0.2987, 83.6853] 0.1208	0.1619 [0.0177, 0.3062]	0.9660

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 2 of 6

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

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

| System Organ Class | Preferred Term | TransCon hGH (N=25) | Daily rhGH (N=13) | Total (N=38) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Metabolism and nutrition disorders		3 (12.0%)	3 (23.1%)	6 (15.8%)	0.4539 [0.0776, 2.6558]	0.5195 [0.1215, 2.2208] 0.3866	-0.1109 [-0.3730, 0.1511]	0.4922
Nervous system disorders		1 (4.0%)	3 (23.1%)	4 (10.5%)	0.1250 [0.0108, 1.4485]	0.1765 [0.0213, 1.4615] 0.0703	-0.1889 [-0.4264, 0.0486]	0.9139
	Headache	0	2 (15.4%)	2 (5.3%)	0.0857 [0.0037, 2.0094]	0.1111 [0.0059, 2.0940] 0.0473	-0.1529 [-0.3487, 0.0428]	0.9980
Eye disorders		0	0	0				0.8133
Skin and subcutaneous tissue disorders		0	0	0				0.3707

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 3 of 6

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

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Any adverse event		73 (97.3%)	37 (92.5%)	110 (95.7%)	1.4906 [0.3170, 7.0084]	1.0254 [0.9256, 1.1360] 0.6130	0.0235 [-0.0721, 0.1192]
Infections and infestations		49 (65.3%)	26 (65.0%)	75 (65.2%)	1.0120 [0.4383, 2.3366]	1.0039 [0.7662, 1.3152] 0.9780	0.0025 [-0.1735, 0.1785]
	Upper respiratory tract infection	35 (46.7%)	22 (55.0%)	57 (49.6%)	0.7060 [0.3223, 1.5464]	0.8473 [0.5890, 1.2190] 0.3831	-0.0841 [-0.2721, 0.1040]
	Bronchitis	8 (10.7%)	2 (5.0%)	10 (8.7%)	2.4103 [0.4586, 12.6687]	2.1200 [0.4953, 9.0735] 0.2936	0.0561 [-0.0372, 0.1494]
	Tonsillitis	4 (5.3%)	4 (10.0%)	8 (7.0%)	0.5064 [0.1196, 2.1446]	0.5330 [0.1408, 2.0177] 0.3524	-0.0467 [-0.1526, 0.0592]
	Pharyngitis	0	0	0			
Investigations		38 (50.7%)	21 (52.5%)	59 (51.3%)	0.9306 [0.4334, 1.9984]	0.9654 [0.6655, 1.4005] 0.8540	-0.0181 [-0.2108, 0.1746]
	Blood glucose increased	13 (17.3%)	12 (30.0%)	25 (21.7%)	0.4711 [0.1856, 1.1956]	0.5794 [0.2981, 1.1264] 0.1124	-0.1260 [-0.2877, 0.0356]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 4 of 6

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

Baseline GH-stimulation strata: > 5 ng/mL

| | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
System Organ Class	Preferred Term	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Insulin-like growth factor increased	22 (29.3%)	2 (5.0%)	24 (20.9%)	7.9515 [1.7635, 35.8532]	5.8582 [1.4524, 23.6284] 0.0022	0.2430 [0.1200, 0.3659]
	Blood alkaline phosphatase increased	2 (2.7%)	4 (10.0%)	6 (5.2%)	0.2311 [0.0384, 1.3887]	0.2650 [0.0522, 1.3462] 0.0884	-0.0736 [-0.1722, 0.0250]
Respiratory, thoracic and mediastinal disorders		27 (36.0%)	10 (25.0%)	37 (32.2%)	1.6705 [0.7147, 3.9046]	1.4381 [0.7732, 2.6749] 0.2293	0.1095 [-0.0645, 0.2835]
	Cough	22 (29.3%)	7 (17.5%)	29 (25.2%)	1.9464 [0.7523, 5.0360]	1.6737 [0.7818, 3.5828] 0.1641	0.1179 [-0.0389, 0.2747]
	Rhinorrhoea	3 (4.0%)	4 (10.0%)	7 (6.1%)	0.3848 [0.0829, 1.7868]	0.3985 [0.0913, 1.7388] 0.2023	-0.0601 [-0.1643, 0.0441]
General disorders and administration site conditions		16 (21.3%)	11 (27.5%)	27 (23.5%)	0.7751 [0.3236, 1.8563]	0.8236 [0.4257, 1.5936] 0.5667	-0.0485 [-0.2174, 0.1205]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:11 Page 5 of 6

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

Baseline GH-stimulation strata: > 5 ng/mL

System Organ Class	Preferred Term	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Pyrexia	12 (16.0%)	8 (20.0%)	20 (17.4%)	0.8393 [0.3170, 2.2224]	0.8657 [0.3898, 1.9229] 0.7244	-0.0268 [-0.1783, 0.1246]
Gastrointestinal disorders		9 (12.0%)	9 (22.5%)	18 (15.7%)	0.4736 [0.1721, 1.3033]	0.5336 [0.2294, 1.2413] 0.1435	-0.1050 [-0.2545, 0.0446]
	Diarrhoea	3 (4.0%)	4 (10.0%)	7 (6.1%)	0.3730 [0.0788, 1.7652]	0.3992 [0.0940, 1.6942] 0.2023	-0.0601 [-0.1630, 0.0428]
Metabolism and nutrition disorders		9 (12.0%)	5 (12.5%)	14 (12.2%)	0.9571 [0.3067, 2.9863]	0.9602 [0.3348, 2.7539] 0.9388	-0.0050 [-0.1343, 0.1244]
Eye disorders		8 (10.7%)	3 (7.5%)	11 (9.6%)	1.4600 [0.3735, 5.7069]	1.4249 [0.3944, 5.1480] 0.5803	0.0319 [-0.0772, 0.1410]
Skin and subcutaneous tissue disorders		8 (10.7%)	1 (2.5%)	9 (7.8%)	4.6279 [0.5585, 38.3506]	4.2739 [0.5508, 33.1628] 0.1236	0.0817 [-0.0035, 0.1668]
Nervous system disorders		0	0	0			
	Headache	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 6 of 6

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

Isolated idiopathic

System Organ Class	Preferred Term	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Any adverse event		81 (97.6%)	44 (93.6%)	125 (96.2%)	3.1008 [0.7037, 13.6629]	1.0743 [0.9694, 1.1905] 0.1212	0.0667 [-0.0268, 0.1602]	0.9982
Infections and infestations		50 (60.2%)	31 (66.0%)	81 (62.3%)	0.7462 [0.3420, 1.6281]	0.9055 [0.6997, 1.1719] 0.4664	-0.0626 [-0.2269, 0.1018]	0.9857
	Upper respiratory tract infection	37 (44.6%)	27 (57.4%)	64 (49.2%)	0.5440 [0.2520, 1.1743]	0.7664 [0.5548, 1.0587] 0.1229	-0.1350 [-0.3024, 0.0323]	0.9950
	Conjunctivitis	0	0	0				0.9862
	Gastroenteritis	0	0	0				0.9819
	Gastroenteritis viral	0	0	0				0.9950
	Nasopharyngitis	0	0	0				0.8968
Investigations		40 (48.2%)	25 (53.2%)	65 (50.0%)	0.8237 [0.4041, 1.6791]	0.9075 [0.6375, 1.2917] 0.5935	-0.0491 [-0.2289, 0.1308]	0.9440
	Blood glucose increased	14 (16.9%)	14 (29.8%)	28 (21.5%)	0.4726 [0.1986, 1.1248]	0.5746 [0.3042, 1.0855] 0.0899	-0.1259 [-0.2766, 0.0248]	0.5146
	Insulin-like growth factor increased	25 (30.1%)	3 (6.4%)	28 (21.5%)	6.1903 [1.7700, 21.6503]	4.7035 [1.4899, 14.8483] 0.0017	0.2357 [0.1145, 0.3570]	0.9992

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 1 of 13

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

Isolated idiopathic

System Organ Class	Preferred Term	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
	Blood glucose abnormal	0	0	0				0.9994
	Liver function test abnormal	0	0	0				0.9950
	Thyroid function test abnormal	0	0	0				0.9950
	Thyroxine free decreased	0	0	0				0.9991
Respiratory, thoracic and mediastinal disorders		29 (34.9%)	12 (25.5%)	41 (31.5%)	1.5524 [0.7008, 3.4387]	1.3612 [0.7683, 2.4116] 0.2782	0.0922 [-0.0693, 0.2537]	0.9999
	Cough	23 (27.7%)	8 (17.0%)	31 (23.8%)	1.8480 [0.7537, 4.5307]	1.6202 [0.7843, 3.3473] 0.1770	0.1054 [-0.0393, 0.2501]	0.9990
	Nasal congestion	0	0	0				0.9950
General disorders and administration site conditions		17 (20.5%)	12 (25.5%)	29 (22.3%)	0.8115 [0.3540, 1.8604]	0.8489 [0.4434, 1.6253] 0.6207	-0.0384 [-0.1929, 0.1162]	0.9760
	Pyrexia	13 (15.7%)	7 (14.9%)	20 (15.4%)	1.1536 [0.4317, 3.0825]	1.1298 [0.4856, 2.6283] 0.7761	0.0192 [-0.1112, 0.1497]	0.9990

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 2 of 13

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

Isolated idiopathic

System Organ Class	Preferred Term	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Gastrointestinal disorders		15 (18.1%)	9 (19.1%)	24 (18.5%)	0.9345 [0.3764, 2.3197]	0.9457 [0.4485, 1.9938] 0.8837	-0.0104 [-0.1513, 0.1304]	0.5889
	Abdominal pain	0	0	0				0.9862
	Diarrhoea	0	0	0				0.9959
	Toothache	0	0	0				0.9862
Metabolism and nutrition disorders		10 (12.0%)	8 (17.0%)	18 (13.8%)	0.6773 [0.2505, 1.8307]	0.7084 [0.2934, 1.7105] 0.4388	-0.0492 [-0.1789, 0.0806]	0.9983
	Hyperuricaemia	0	0	0				0.9979
Blood and lymphatic system disorders		0	0	0				0.9999
	Anaemia	0	0	0				0.9442
	Hypochromic anaemia	0	0	0				0.9991
Endocrine disorders		0	0	0				0.9842
	Precocious puberty	0	0	0				0.9950
Eye disorders		0	0	0				0.2136

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 3 of 13

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

Isolated idiopathic

System Organ Class	Preferred Term	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
	Papilloedema	0	0	0				1.0000
	Refraction disorder	0	0	0				0.8018
	Vernal keratoconjunctivitis	0	0	0				0.9950
Nervous system disorders		0	0	0				0.9919
	Headache	0	0	0				0.9997
Reproductive system and breast disorders		0	0	0				0.9997
Skin and subcutaneous tissue disorders		0	0	0				0.5140
	Rash	0	0	0				0.9950

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 4 of 13

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

Isolated organic (determined by abnormal MRI)

System Organ Class	Preferred Term	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Any adverse event		14 (100.0%)	5 (100.0%)	19 (100.0%)	0.7333 [0.0214, 25.0882]	0.8333 [0.5827, 1.1919] 0.5637	-0.0667 [-0.1929, 0.0596]
Infections and infestations		10 (71.4%)	4 (80.0%)	14 (73.7%)	0.6250 [0.0405, 9.6498]	0.9146 [0.5635, 1.4846] 0.7462	-0.0680 [-0.4462, 0.3102]
	Upper respiratory tract infection	7 (50.0%)	3 (60.0%)	10 (52.6%)	0.7000 [0.0975, 5.0252]	0.8361 [0.3199, 2.1849] 0.7239	-0.0971 [-0.6269, 0.4327]
	Nasopharyngitis	1 (7.1%)	2 (40.0%)	3 (15.8%)	0.1081 [0.0054, 2.1531]	0.1951 [0.0254, 1.4992] 0.1047	-0.3204 [-0.7639, 0.1231]
	Gastroenteritis	1 (7.1%)	1 (20.0%)	2 (10.5%)	0.2500 [0.0073, 8.5598]	0.4000 [0.0428, 3.7375] 0.4624	-0.1165 [-0.4570, 0.2240]
	Conjunctivitis	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
	Gastroenteritis viral	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
Investigations		9 (64.3%)	3 (60.0%)	12 (63.2%)	1.2571 [0.1670, 9.4648]	1.0968 [0.4774, 2.5198] 0.8127	0.0583 [-0.4602, 0.5767]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 5 of 13

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

Isolated organic (determined by abnormal MRI)

System Organ Class	Preferred Term	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Blood glucose increased	2 (14.3%)	3 (60.0%)	5 (26.3%)	0.0886 [0.0064, 1.2176]	0.2258 [0.0520, 0.9797] 0.0477	-0.4660 [-0.9196, -0.0124]
	Insulin-like growth factor increased	4 (28.6%)	0	4 (21.1%)	2.9341 [0.2579, 33.3748]	2.1964 [0.3069, 15.7212] 0.1514	0.3010 [0.0629, 0.5390]
	Blood glucose abnormal	1 (7.1%)	2 (40.0%)	3 (15.8%)	0.1905 [0.0189, 1.9234]	0.1905 [0.0195, 1.8590] 0.1000	-0.3301 [-0.8170, 0.1568]
	Liver function test abnormal	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
	Thyroid function test abnormal	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
	Thyroxine free decreased	0	0	0			
Respiratory, thoracic and mediastinal disorders		4 (28.6%)	1 (20.0%)	5 (26.3%)	1.5510 [0.1446, 16.6364]	1.4286 [0.2011, 10.1468] 0.7194	0.0874 [-0.3559, 0.5306]
	Cough	4 (28.6%)	0	4 (21.1%)	2.8591 [0.2649, 30.8587]	2.2456 [0.3207, 15.7246] 0.1942	0.2913 [0.0537, 0.5288]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 6 of 13

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

Isolated organic (determined by abnormal MRI)

System Organ Class	Preferred Term	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Nasal congestion	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
Eye disorders		2 (14.3%)	2 (40.0%)	4 (21.1%)	0.3500 [0.0507, 2.4142]	0.3500 [0.0450, 2.7250] 0.2605	-0.2524 [-0.7738, 0.2689]
	Refraction disorder	1 (7.1%)	1 (20.0%)	2 (10.5%)	0.3500 [0.0216, 5.6698]	0.3500 [0.0192, 6.3761] 0.4581	-0.1262 [-0.5160, 0.2636]
	Vernal keratoconjunctivitis	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
	Papilloedema	0	0	0			
Gastrointestinal disorders		2 (14.3%)	2 (40.0%)	4 (21.1%)	0.2569 [0.0253, 2.6048]	0.3415 [0.0579, 2.0131] 0.2368	-0.2621 [-0.7371, 0.2129]
	Abdominal pain	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

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

Isolated organic (determined by abnormal MRI)

					Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Toothache	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
	Diarrhoea	0	0	0			
General disorders and administration site conditions		3 (21.4%)	1 (20.0%)	4 (21.1%)	1.0500 [0.1051, 10.4859]	1.0500 [0.1007, 10.9501] 0.9650	0.0097 [-0.4445, 0.4640]
	Pyrexia	3 (21.4%)	1 (20.0%)	4 (21.1%)	1.0500 [0.1051, 10.4859]	1.0500 [0.1007, 10.9501] 0.9650	0.0097 [-0.4445, 0.4640]
Skin and subcutaneous tissue disorders		2 (14.3%)	1 (20.0%)	3 (15.8%)	0.7619 [0.0698, 8.3160]	0.7619 [0.0756, 7.6809] 0.8058	-0.0485 [-0.4890, 0.3919]
	Rash	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
Endocrine disorders		1 (7.1%)	1 (20.0%)	2 (10.5%)	0.2500 [0.0104, 5.9847]	0.3333 [0.0289, 3.8416] 0.3918	-0.1359 [-0.4999, 0.2281]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

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

Isolated organic (determined by abnormal MRI)

		TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Endocrine disorders	Precocious puberty	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
Reproductive system and breast disorders		2 (14.3%)	0	2 (10.5%)	1.4275 [0.1208, 16.8721]	1.3467 [0.1693, 10.7131] 0.3919	0.1456 [-0.0392, 0.3305]
Nervous system disorders		0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
	Headache	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
Blood and lymphatic system disorders		0	0	0			
	Anaemia	0	0	0			
	Hypochromic anaemia	0	0	0			
Metabolism and nutrition disorders		0	0	0			
	Hyperuricaemia	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

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

Multiple pituitary hormone deficiencies

System Organ Class	Preferred Term	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Any adverse event		3 (100.0%)	1 (100.0%)	4 (100.0%)			
Blood and lymphatic system disorders		1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
	Anaemia	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
	Hypochromic anaemia	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]
Eye disorders		1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
	Papilloedema	1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
	Refraction disorder	0	0	0			
	Vernal keratoconjunctivitis	0	0	0			
Investigations		1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 10 of 13

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

Multiple pituitary hormone deficiencies

		TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Blood glucose increased	1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
	Thyroxine free decreased	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]
	Blood glucose abnormal	0	0	0			
	Insulin-like growth factor increased	0	0	0			
	Liver function test abnormal	0	0	0			
	Thyroid function test abnormal	0	0	0			
Gastrointestinal disorders		0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
	Diarrhoea	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
	Abdominal pain	0	0	0			
	Toothache	0	0	0			

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

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

Multiple pituitary hormone deficiencies

					Lonapegsomatropin vs. Daily rhGH [a]		
		TransCon				RR	
		hGH	Daily rhGH	Total	OR	[95 %-CI] [b]	RD
System Organ Class	Preferred Term	(N=3)	(N=1)	(N=4)	[95 %-CI] [b]	p-value[c]	[95 %-CI] [b]
Metabolism and nutrition disorders		1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]
	Hyperuricaemia	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]
Nervous system disorders		0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
	Headache	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
Endocrine disorders		0	0	0			
	Precocious puberty	0	0	0			
General disorders and administration site conditions		0	0	0			
	Pyrexia	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 12 of 13

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

Multiple pituitary hormone deficiencies

| | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
| | | TransCon hGH (N=3) | Daily rhGH (N=1) | Total (N=4) | OR [95 %-CI] [b] | RR [95 %-CI] [b] p-value [c] | RD [95 %-CI] [b] |
System Organ Class	Preferred Term						
Infections and infestations		0	0	0			
	Conjunctivitis	0	0	0			
	Gastroenteritis	0	0	0			
	Gastroenteritis viral	0	0	0			
	Nasopharyngitis	0	0	0			
	Upper respiratory tract infection	0	0	0			
Reproductive system and breast disorders		0	0	0			
Respiratory, thoracic and mediastinal disorders		0	0	0			
	Cough	0	0	0			
	Nasal congestion	0	0	0			
Skin and subcutaneous tissue disorders		0	0	0			
	Rash	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 13 of 13

Table 1.28 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated
GH concentration at baseline, AE: >=10% in any treatment group
Safety Population

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

System Organ Class	Preferred Term	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Any adverse event		69 (97.2%)	36 (94.7%)	105 (96.3%)	3.8647 [0.6730, 22.1949]	1.0800 [0.9669, 1.2063] 0.1100	0.0720 [-0.0285, 0.1725]	0.3981
Infections and infestations		45 (63.4%)	23 (60.5%)	68 (62.4%)	1.1231 [0.4819, 2.6175]	1.0414 [0.7724, 1.4041] 0.7896	0.0251 [-0.1585, 0.2087]	0.0913
	Upper respiratory tract infection	32 (45.1%)	20 (52.6%)	52 (47.7%)	0.7060 [0.3082, 1.6175]	0.8502 [0.5832, 1.2395] 0.4160	-0.0791 [-0.2666, 0.1084]	0.3425
	Gastroenteritis	0	0	0				0.9499
	Nasopharyngitis	0	0	0				0.9540
	Respiratory tract infection	0	0	0				0.1862
	Tonsillitis	0	0	0				0.5607
Investigations		34 (47.9%)	22 (57.9%)	56 (51.4%)	0.6758 [0.3086, 1.4800]	0.8269 [0.5708, 1.1978] 0.3238	-0.1001 [-0.2981, 0.0980]	0.3250
	Blood glucose increased	11 (15.5%)	13 (34.2%)	24 (22.0%)	0.3478 [0.1361, 0.8890]	0.4556 [0.2278, 0.9111] 0.0257	-0.1858 [-0.3571, -0.0145]	0.6475
	Insulin-like growth factor increased	21 (29.6%)	3 (7.9%)	24 (22.0%)	4.8139 [1.3483, 17.1876]	3.7252 [1.1812, 11.7484] 0.0093	0.2150 [0.0783, 0.3518]	0.9760

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 1 of 7

Table 1.28 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated
GH concentration at baseline, AE: >=10% in any treatment group
Safety Population

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

| System Organ Class | Preferred Term | TransCon hGH (N=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
	Low density lipoprotein increased	0	0	0				0.9564
Respiratory, thoracic and mediastinal disorders		23 (32.4%)	7 (18.4%)	30 (27.5%)	2.1227 [0.8106, 5.5583]	1.7510 [0.8300, 3.6941] 0.1238	0.1385 [-0.0253, 0.3022]	0.2270
	Cough	20 (28.2%)	2 (5.3%)	22 (20.2%)	7.1647 [1.5631, 32.8415]	5.3187 [1.3178, 21.4670] 0.0048	0.2278 [0.1020, 0.3537]	0.0090
	Rhinorrhoea	0	0	0				0.9564
General disorders and administration site conditions		14 (19.7%)	10 (26.3%)	24 (22.0%)	0.6899 [0.2719, 1.7506]	0.7521 [0.3700, 1.5287] 0.4372	-0.0650 [-0.2324, 0.1023]	0.4992
	Pyrexia	11 (15.5%)	6 (15.8%)	17 (15.6%)	0.9791 [0.3313, 2.8939]	0.9824 [0.3941, 2.4490] 0.9698	-0.0028 [-0.1460, 0.1404]	0.5983
Gastrointestinal disorders		14 (19.7%)	9 (23.7%)	23 (21.1%)	0.7981 [0.3112, 2.0468]	0.8360 [0.3981, 1.7555] 0.6375	-0.0389 [-0.2041, 0.1263]	0.5939
	Diarrhoea	0	0	0				0.3663

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 2 of 7

Table 1.28 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated
GH concentration at baseline, AE: >=10% in any treatment group
Safety Population

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

					Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders		9 (12.7%)	3 (7.9%)	12 (11.0%)	1.7072 [0.4335, 6.7239]	1.6150 [0.4661, 5.5956] 0.4430	0.0485 [-0.0669, 0.1640]	0.4490
Metabolism and nutrition disorders		6 (8.5%)	6 (15.8%)	12 (11.0%)	0.4895 [0.1439, 1.6648]	0.5409 [0.1898, 1.5415] 0.2500	-0.0722 [-0.2035, 0.0591]	0.2523
	Hypercholesterolaemia	0	0	0				0.9580
	Hypertriglyceridaemia	0	0	0				0.9769
Skin and subcutaneous tissue disorders		9 (12.7%)	2 (5.3%)	11 (10.1%)	2.5512 [0.5315, 12.2451]	2.4102 [0.5356, 10.8454] 0.2268	0.0737 [-0.0324, 0.1798]	0.9784
Nervous system disorders		1 (1.4%)	5 (13.2%)	6 (5.5%)	0.0884 [0.0097, 0.8087]	0.1091 [0.0135, 0.8808] 0.0105	-0.1165 [-0.2264, -0.0065]	0.3622
	Headache	0	4 (10.5%)	4 (3.7%)	0.0512 [0.0026, 0.9959]	0.0617 [0.0035, 1.1002] 0.0056	-0.1046 [-0.2019, -0.0072]	0.9987

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 3 of 7

Table 1.28 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated
GH concentration at baseline, AE: >=10% in any treatment group
Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL

| | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
System Organ Class	Preferred Term	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Any adverse event		29 (100.0%)	14 (93.3%)	43 (97.7%)	1.0417 [0.0929, 11.6857]	1.0028 [0.8485, 1.1852] 0.9734	0.0026 [-0.1546, 0.1599]
Infections and infestations		15 (51.7%)	12 (80.0%)	27 (61.4%)	0.2068 [0.0389, 1.1008]	0.6526 [0.4394, 0.9693] 0.0604	-0.2771 [-0.5258, -0.0284]
	Upper respiratory tract infection	12 (41.4%)	10 (66.7%)	22 (50.0%)	0.3271 [0.0810, 1.3201]	0.6261 [0.3645, 1.0755] 0.1083	-0.2478 [-0.5344, 0.0388]
	Tonsillitis	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.4941 [0.0625, 3.9078]	0.5275 [0.0831, 3.3486] 0.4968	-0.0630 [-0.2593, 0.1332]
	Nasopharyngitis	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2143 [0.0162, 2.8392]	0.2667 [0.0283, 2.5095] 0.2239	-0.0968 [-0.2764, 0.0829]
	Respiratory tract infection	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2386 [0.0198, 2.8774]	0.2637 [0.0264, 2.6340] 0.2303	-0.0982 [-0.2833, 0.0868]
	Gastroenteritis	0	2 (13.3%)	2 (4.5%)	0.1553 [0.0148, 1.6293]	0.1826 [0.0205, 1.6219] 0.0491	-0.1334 [-0.3055, 0.0387]
Investigations		16 (55.2%)	7 (46.7%)	23 (52.3%)	1.3973 [0.4049, 4.8222]	1.1818 [0.6257, 2.2322] 0.6010	0.0850 [-0.2287, 0.3988]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 4 of 7

Table 1.28 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated
GH concentration at baseline, AE: >=10% in any treatment group
Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL

| | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
| | | TransCon hGH (N=29) | Daily rhGH (N=15) | Total (N=44) | OR [95 %-CI] [b] | RR [95 %-CI] [b] p-value [c] | RD [95 %-CI] [b] |
System Organ Class	Preferred Term						
Investigations	Blood glucose increased	6 (20.7%)	5 (33.3%)	11 (25.0%)	0.4385 [0.0919, 2.0915]	0.6070 [0.2431, 1.5158] 0.3074	-0.1320 [-0.3887, 0.1248]
	Insulin-like growth factor increased	8 (27.6%)	0	8 (18.2%)	6.4245 [0.7344, 56.2043]	4.8317 [0.6642, 35.1500] 0.0267	0.2771 [0.1143, 0.4399]
	Low density lipoprotein increased	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.5217 [0.0749, 3.6363]	0.5217 [0.0758, 3.5897] 0.4905	-0.0645 [-0.2700, 0.1410]
Respiratory, thoracic and mediastinal disorders		10 (34.5%)	6 (40.0%)	16 (36.4%)	0.8079 [0.2356, 2.7701]	0.8650 [0.3790, 1.9739] 0.7286	-0.0543 [-0.3696, 0.2611]
	Cough	7 (24.1%)	6 (40.0%)	13 (29.5%)	0.5039 [0.1389, 1.8282]	0.6058 [0.2414, 1.5204] 0.2863	-0.1584 [-0.4615, 0.1447]
	Rhinorrhoea	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.5217 [0.0749, 3.6363]	0.5217 [0.0758, 3.5897] 0.4905	-0.0645 [-0.2700, 0.1410]
General disorders and administration site conditions		6 (20.7%)	3 (20.0%)	9 (20.5%)	1.3017 [0.2773, 6.1111]	1.2206 [0.3743, 3.9801] 0.7428	0.0440 [-0.2076, 0.2956]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:11 Page 5 of 7

Table 1.28 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated
GH concentration at baseline, AE: >=10% in any treatment group
Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL

System Organ Class	Preferred Term	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
					OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Pyrexia	5 (17.2%)	2 (13.3%)	7 (15.9%)	1.7041 [0.3015, 9.6321]	1.5604 [0.3579, 6.8030] 0.5499	0.0748 [-0.1525, 0.3021]
Metabolism and nutrition disorders		6 (20.7%)	2 (13.3%)	8 (18.2%)	1.5652 [0.3282, 7.4653]	1.5652 [0.3228, 7.5898] 0.5348	0.0762 [-0.1748, 0.3273]
	Hypercholesterola emia	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.5217 [0.0749, 3.6363]	0.5217 [0.0758, 3.5897] 0.4905	-0.0645 [-0.2700, 0.1410]
	Hypertriglycerida emia	3 (10.3%)	0	3 (6.8%)	4.7600 [0.2169, 104.4693]	3.9375 [0.2281, 67.9639] 0.1846	0.1056 [-0.0062, 0.2173]
Gastrointestinal disorders		3 (10.3%)	3 (20.0%)	6 (13.6%)	0.4615 [0.0799, 2.6645]	0.5221 [0.1209, 2.2551] 0.3910	-0.0953 [-0.3247, 0.1341]
	Diarrhoea	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2386 [0.0198, 2.8774]	0.2637 [0.0264, 2.6340] 0.2303	-0.0982 [-0.2833, 0.0868]
Eye disorders		0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:11 Page 6 of 7

Table 1.28 Treatment Emergent Adverse Events: Incidences by System Organ Class and Preferred Term, subgroup analysis by peak stimulated
GH concentration at baseline, AE: >=10% in any treatment group
Safety Population

Peak stimulated GH concentration at baseline: >= 8 ng/mL

| | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
| | | TransCon hGH (N=29) | Daily rhGH (N=15) | Total (N=44) | OR [95 %-CI] [b] | RR [95 %-CI] [b] p-value [c] | RD [95 %-CI] [b] |
System Organ Class	Preferred Term						
Nervous system disorders		0	0	0			
	Headache	0	0	0			
Skin and subcutaneous tissue disorders		0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-inc-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Any adverse event			41 (97.6%)	21 (95.5%)	62 (96.9%)				
		Mild	37 (88.1%)	19 (86.4%)	56 (87.5%)	1.1684 [0.2519, 5.4205]	1.0201 [0.8353, 1.2457] 0.8435	0.0173 [-0.1563, 0.1910]	0.9280
		Moderate	3 (7.1%)	2 (9.1%)	5 (7.8%)	0.7692 [0.1187, 4.9842]	0.7857 [0.1417, 4.3582] 0.7844	-0.0195 [-0.1626, 0.1237]	0.7984
		Severe	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
Infections and infestations			32 (76.2%)	19 (86.4%)	51 (79.7%)				
		Mild	30 (71.4%)	17 (77.3%)	47 (73.4%)	0.7353 [0.2212, 2.4437]	0.9244 [0.6872, 1.2435] 0.6179	-0.0584 [-0.2805, 0.1637]	0.8283
		Moderate	1 (2.4%)	2 (9.1%)	3 (4.7%)	0.2439 [0.0209, 2.8527]	0.2619 [0.0251, 2.7308] 0.2314	-0.0671 [-0.1958, 0.0616]	0.6862
		Severe	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 1 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Upper respiratory tract infection		23 (54.8%)	19 (86.4%)	42 (65.6%)				
		Mild	23 (54.8%)	17 (77.3%)	40 (62.5%)	0.3560 [0.1108, 1.1445]	0.7087 [0.4963, 1.0120] 0.0796	-0.2251 [-0.4560, 0.0058]	0.1118
		Moderate	0	2 (9.1%)	2 (3.1%)	0.0965 [0.0044, 2.1028]	0.1070 [0.0054, 2.1355] 0.0489	-0.0909 [-0.2110, 0.0292]	0.9974
		Severe	0	0	0				
	Bronchitis		8 (19.0%)	2 (9.1%)	10 (15.6%)				
		Mild	7 (16.7%)	2 (9.1%)	9 (14.1%)	2.0000 [0.3785, 10.5685]	1.8333 [0.4155, 8.0892] 0.4113	0.0758 [-0.0890, 0.2405]	0.9985
		Moderate	0	0	0				0.9776
		Severe	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
	Tonsillitis		3 (7.1%)	2 (9.1%)	5 (7.8%)				
		Mild	3 (7.1%)	2 (9.1%)	5 (7.8%)	0.7692 [0.1187, 4.9842]	0.7857 [0.1417, 4.3582] 0.7844	-0.0195 [-0.1626, 0.1237]	0.9834
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 2 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Herpangina		3 (7.1%)	0	3 (4.7%)				
		Mild	3 (7.1%)	0	3 (4.7%)	3.9873 [0.1969, 80.7365]	3.7442 [0.2020, 69.3949] 0.2027	0.0714 [-0.0065, 0.1493]	0.9709
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasopharyngitis		1 (2.4%)	2 (9.1%)	3 (4.7%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.7131
		Moderate	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Severe	0	0	0				
	Pneumonia		2 (4.8%)	1 (4.5%)	3 (4.7%)				
		Mild	2 (4.8%)	1 (4.5%)	3 (4.7%)	1.0500 [0.0899, 12.2640]	1.0476 [0.1005, 10.9233] 0.9692	0.0022 [-0.1061, 0.1104]	0.9703
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 3 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Conjunctivitis		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastroenteritis		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Hand-foot-and-mouth disease		2 (4.8%)	0	2 (3.1%)				
		Mild	2 (4.8%)	0	2 (3.1%)	2.7778 [0.1277, 60.4271]	2.6744 [0.1340, 53.3879] 0.3022	0.0476 [-0.0168, 0.1120]	0.9763
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 4 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Laryngitis		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis media		2 (4.8%)	0	2 (3.1%)				
		Mild	2 (4.8%)	0	2 (3.1%)	2.7778 [0.1277, 60.4271]	2.6744 [0.1340, 53.3879] 0.3022	0.0476 [-0.0168, 0.1120]	0.9574
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis media acute		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Pharyngitis		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9751
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 5 of 108

Table 1.18 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Respiratory tract infection		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.6624
		Moderate	0	0	0				
		Severe	0	0	0				
	Bacterial infection		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Folliculitis		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 6 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Gastroenteritis viral		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal bacterial infection		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Herpes virus infection		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 7 of 108

Anhang 4-H   Seite 76 von 682

Table 1.18 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=42) | Daily rhGH (N=22) | Total (N=64) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Infectious mononucleosis		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Mumps		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Oral herpes		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9473
		Moderate	0	0	0				
		Severe	0	0	0				
	Periodontitis		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 8 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Peritonsillar abscess		0	1 (4.5%)	1 (1.6%)				
		Mild	0	0	0				
		Moderate	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Severe	0	0	0				
	Pulpitis dental		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Sinobronchitis		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 9 of 108

Table 1.18 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=42) | Daily rhGH (N=22) | Total (N=64) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Sinusitis		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				0.9804
		Severe	0	0	0				
	Subcutaneous abscess		1 (2.4%)	0	1 (1.6%)				
		Mild	0	0	0				
		Moderate	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Severe	0	0	0				
	Varicella		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9442
		Moderate	0	0	0				
		Severe	0	0	0				
	Abscess limb		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 10 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Chronic sinusitis		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Chronic tonsillitis		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Hordeolum		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Influenza		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9776
		Severe	0	0	0				
	Myringitis		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 11 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Rhinitis		0	0	0				
		Mild	0	0	0				0.9999
		Moderate	0	0	0				
		Severe	0	0	0				
	Tonsillitis bacterial		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				0.9776
	Tracheitis		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Urinary tract infection		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 12 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations			24 (57.1%)	9 (40.9%)	33 (51.6%)				
		Mild	24 (57.1%)	9 (40.9%)	33 (51.6%)	1.9259 [0.6761, 5.4861]	1.3968 [0.7928, 2.4611] 0.2207	0.1623 [-0.0918, 0.4165]	0.0380
		Moderate	0	0	0				
		Severe	0	0	0				
	Insulin-like growth factor increased		17 (40.5%)	1 (4.5%)	18 (28.1%)				
		Mild	17 (40.5%)	1 (4.5%)	18 (28.1%)	14.2800 [1.7512, 116.4467]	8.9048 [1.2673, 62.5704] 0.0026	0.3593 [0.1872, 0.5314]	0.3202
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose increased		4 (9.5%)	4 (18.2%)	8 (12.5%)				
		Mild	4 (9.5%)	4 (18.2%)	8 (12.5%)	0.4737 [0.1062, 2.1125]	0.5238 [0.1447, 1.8959] 0.3237	-0.0866 [-0.2706, 0.0974]	0.7385
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 13 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood alkaline phosphatase increased		2 (4.8%)	3 (13.6%)	5 (7.8%)				
		Mild	2 (4.8%)	3 (13.6%)	5 (7.8%)	0.3167 [0.0488, 2.0560]	0.3492 [0.0630, 1.9370] 0.2125	-0.0887 [-0.2459, 0.0685]	0.7678
		Moderate	0	0	0				
		Severe	0	0	0				
	Low density lipoprotein increased		3 (7.1%)	1 (4.5%)	4 (6.3%)				
		Mild	3 (7.1%)	1 (4.5%)	4 (6.3%)	1.6154 [0.1580, 16.5120]	1.5714 [0.1735, 14.2334] 0.6858	0.0260 [-0.0908, 0.1428]	0.1708
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood iron increased		1 (2.4%)	2 (9.1%)	3 (4.7%)				
		Mild	1 (2.4%)	2 (9.1%)	3 (4.7%)	0.2439 [0.0209, 2.8527]	0.2619 [0.0251, 2.7308] 0.2314	-0.0671 [-0.1958, 0.0616]	0.9767
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood phosphorus increased		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9740
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood triglycerides increased		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9708
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood uric acid increased		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.6982
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 15 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Eosinophil count increased		2 (4.8%)	0	2 (3.1%)				
		Mild	2 (4.8%)	0	2 (3.1%)	2.7778 [0.1277, 60.4271]	2.6744 [0.1340, 53.3879] 0.3022	0.0476 [-0.0168, 0.1120]	0.9698
		Moderate	0	0	0				
		Severe	0	0	0				
	Tri-iodothyronine free increased		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Alanine aminotransferase increased		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9484
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Basophil count increased		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood cholesterol increased		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose abnormal		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9574
		Moderate	0	0	0				
		Severe	0	0	0				

Lonapegsomatropin vs. Daily rhGH [a]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood lactate dehydrogenase increased		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood potassium increased		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood pressure increased		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 18 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood thyroid stimulating hormone increased		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Cortisol decreased		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9733
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram ST segment abnormal		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 19 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Electrocardiogram T wave peaked		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Haemoglobin decreased		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Aspartate aminotransferase increased		0	0	0				
		Mild	0	0	0				0.9788
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood urea increased		0	0	0				
		Mild	0	0	0				0.9722
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram high voltage		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Hepatic enzyme abnormal		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Hepatic enzyme increased		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 21 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Lipids increased		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Liver function test abnormal		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Thyroid function test abnormal		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Thyroxine free decreased		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 22 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	White blood cell count decreased		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
Respiratory, thoracic and mediastinal disorders			18 (42.9%)	5 (22.7%)	23 (35.9%)				
		Mild	18 (42.9%)	4 (18.2%)	22 (34.4%)	3.3750 [0.9729, 11.7081]	2.3571 [0.9091, 6.1116] 0.0502	0.2468 [0.0268, 0.4667]	0.2074
		Moderate	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9993
		Severe	0	0	0				
	Cough		15 (35.7%)	3 (13.6%)	18 (28.1%)				
		Mild	15 (35.7%)	2 (9.1%)	17 (26.6%)	5.5556 [1.1390, 27.0982]	3.9286 [0.9861, 15.6516] 0.0231	0.2662 [0.0780, 0.4545]	0.2613

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9993
		Severe	0	0	0				
	Rhinorrhoea		3 (7.1%)	1 (4.5%)	4 (6.3%)				
		Mild	3 (7.1%)	1 (4.5%)	4 (6.3%)	1.6154 [0.1580, 16.5120]	1.5714 [0.1735, 14.2334] 0.6858	0.0260 [-0.0908, 0.1428]	0.1708
		Moderate	0	0	0				
		Severe	0	0	0				
	Rhinitis allergic		2 (4.8%)	1 (4.5%)	3 (4.7%)				
		Mild	2 (4.8%)	1 (4.5%)	3 (4.7%)	1.0500 [0.0899, 12.2640]	1.0476 [0.1005, 10.9233] 0.9692	0.0022 [-0.1061, 0.1104]	0.7168
		Moderate	0	0	0				
		Severe	0	0	0				
	Asthma		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9708
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 24 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Allergic cough		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal obstruction		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 25 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Productive cough		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Sleep apnoea syndrome		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal congestion		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Oropharyngeal pain		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 26 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions			9 (21.4%)	4 (18.2%)	13 (20.3%)				
		Mild	8 (19.0%)	3 (13.6%)	11 (17.2%)	1.4902 [0.3528, 6.2945]	1.3968 [0.4113, 4.7433] 0.5887	0.0541 [-0.1321, 0.2403]	0.2351
		Moderate	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9708
		Severe	0	0	0				
	Pyrexia		7 (16.7%)	3 (13.6%)	10 (15.6%)				
		Mild	6 (14.3%)	2 (9.1%)	8 (12.5%)	1.6667 [0.3072, 9.0422]	1.5714 [0.3455, 7.1483] 0.5537	0.0519 [-0.1081, 0.2120]	0.5979
		Moderate	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9982
		Severe	0	0	0				
	Injection site erythema		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9442
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administratio n site conditions	Injection site haemorrhage		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site pain		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site pruritus		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9747
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site reaction		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				0.9776
		Severe	0	0	0				
	Injection site bruising		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site swelling		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 29 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Peripheral swelling		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
Gastrointestinal disorders			5 (11.9%)	6 (27.3%)	11 (17.2%)				
		Mild	5 (11.9%)	6 (27.3%)	11 (17.2%)	0.3604 [0.0959, 1.3541]	0.4365 [0.1499, 1.2711] 0.1246	-0.1537 [-0.3640, 0.0566]	0.2077
		Moderate	0	0	0				
		Severe	0	0	0				
	Diarrhoea		3 (7.1%)	2 (9.1%)	5 (7.8%)				
		Mild	3 (7.1%)	2 (9.1%)	5 (7.8%)	0.7692 [0.1187, 4.9842]	0.7857 [0.1417, 4.3582] 0.7844	-0.0195 [-0.1626, 0.1237]	0.7464
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 30 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Enteritis		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal pain		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9442
		Moderate	0	0	0				
		Severe	0	0	0				
	Constipation		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyspepsia		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9739
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 31 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Gastrointestinal disorder		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal distension		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal pain upper		0	0	0				
		Mild	0	0	0				0.9788
		Moderate	0	0	0				
		Severe	0	0	0				
	Nausea		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 32 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Noninfective gingivitis		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Toothache		0	0	0				
		Mild	0	0	0				0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Vomiting		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
Metabolism and nutrition disorders			7 (16.7%)	1 (4.5%)	8 (12.5%)				
		Mild	7 (16.7%)	1 (4.5%)	8 (12.5%)	4.2000 [0.4824, 36.5650]	3.6667 [0.4812, 27.9408] 0.1671	0.1212 [-0.0212, 0.2636]	0.0441
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 33 of 108

Table 1.18 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders	Hypercholesterolaemia		2 (4.8%)	1 (4.5%)	3 (4.7%)				
		Mild	2 (4.8%)	1 (4.5%)	3 (4.7%)	1.0500 [0.0899, 12.2640]	1.0476 [0.1005, 10.9233] 0.9692	0.0022 [-0.1061, 0.1104]	0.4226
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypertriglyceridaemia		3 (7.1%)	0	3 (4.7%)				
		Mild	3 (7.1%)	0	3 (4.7%)	3.9873 [0.1969, 80.7365]	3.7442 [0.2020, 69.3949] 0.2027	0.0714 [-0.0065, 0.1493]	0.9730
		Moderate	0	0	0				
		Severe	0	0	0				
	Decreased appetite		2 (4.8%)	0	2 (3.1%)				
		Mild	2 (4.8%)	0	2 (3.1%)	2.7778 [0.1277, 60.4271]	2.6744 [0.1340, 53.3879] 0.3022	0.0476 [-0.0168, 0.1120]	0.9574
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders	Hyperuricaemia		1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9708
		Moderate	0	0	0				
		Severe	0	0	0				
	Calcium deficiency		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperglycaemia		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperlipidaemia		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.

Table 1.18 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders			5 (11.9%)	0	5 (7.8%)				
		Mild	5 (11.9%)	0	5 (7.8%)	6.6000 [0.3483, 125.0769]	5.8837 [0.3402, 101.7613] 0.0945	0.1190 [0.0211, 0.2170]	0.9689
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria		2 (4.8%)	0	2 (3.1%)				
		Mild	2 (4.8%)	0	2 (3.1%)	2.7778 [0.1277, 60.4271]	2.6744 [0.1340, 53.3879] 0.3022	0.0476 [-0.0168, 0.1120]	0.9972
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 36 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Skin and subcutaneous tissue disorders	Dermatitis allergic		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9747
		Moderate	0	0	0				
		Severe	0	0	0				
	Eczema		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria chronic		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Urticaria papular		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis contact		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyshidrotic eczema		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Rash		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 38 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Blood and lymphatic system disorders			3 (7.1%)	1 (4.5%)	4 (6.3%)				
		Mild	3 (7.1%)	1 (4.5%)	4 (6.3%)	1.6154 [0.1580, 16.5120]	1.5714 [0.1735, 14.2334] 0.6858	0.0260 [-0.0908, 0.1428]	0.8113
		Moderate	0	0	0				0.9776
		Severe	0	0	0				
	Lymphadenitis		2 (4.8%)	0	2 (3.1%)				
		Mild	2 (4.8%)	0	2 (3.1%)	2.7778 [0.1277, 60.4271]	2.6744 [0.1340, 53.3879] 0.3022	0.0476 [-0.0168, 0.1120]	0.9763
		Moderate	0	0	0				
		Severe	0	0	0				
	Anaemia		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Blood and lymphatic system disorders	Granulocytopenia		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypochromic anaemia		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Thymus disorder		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9776
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders			2 (4.8%)	2 (9.1%)	4 (6.3%)				
		Mild	2 (4.8%)	2 (9.1%)	4 (6.3%)	0.5000 [0.0655, 3.8152]	0.5238 [0.0791, 3.4703] 0.5002	-0.0433 [-0.1796, 0.0930]	0.2994
		Moderate	0	0	0				0.9776
		Severe	0	0	0				
	Conjunctivitis allergic		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Myopia		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Refraction disorder		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9704
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 41 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders	Vernal keratoconjunctivitis		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Corneal epithelium defect		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye pain		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye swelling		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9776
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 42 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders	Papilloedema		0	0	0				
		Mild	0	0	0				0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Vitreous opacities		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Xerophthalmia		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
Injury, poisoning and procedural complications			2 (4.8%)	2 (9.1%)	4 (6.3%)				
		Mild	1 (2.4%)	2 (9.1%)	3 (4.7%)	0.2439 [0.0209, 2.8527]	0.2619 [0.0251, 2.7308] 0.2314	-0.0671 [-0.1958, 0.0616]	0.9677
		Moderate	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 43 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Injury, poisoning and procedural complications	Animal scratch		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye injury		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Head injury		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9442
		Moderate	0	0	0				
		Severe	0	0	0				
	Skin laceration		1 (2.4%)	0	1 (1.6%)				
		Mild	0	0	0				0.9776

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 44 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Injury, poisoning and procedural complications	Skin laceration	Moderate	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Severe	0	0	0				
	Joint injury		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Ligament sprain		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
Ear and labyrinth disorders			1 (2.4%)	1 (4.5%)	2 (3.1%)				
		Mild	1 (2.4%)	1 (4.5%)	2 (3.1%)	0.5122 [0.0305, 8.6039]	0.5238 [0.0344, 7.9786] 0.6391	-0.0216 [-0.1201, 0.0769]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Ear and labyrinth disorders	Cerumen impaction		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Motion sickness		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
Reproductive system and breast disorders			2 (4.8%)	0	2 (3.1%)				
		Mild	2 (4.8%)	0	2 (3.1%)	2.7778 [0.1277, 60.4271]	2.6744 [0.1340, 53.3879] 0.3022	0.0476 [-0.0168, 0.1120]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Reproductive system and breast disorders	Balanoposthitis		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Pelvic fluid collection		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Gynaecomastia		0	0	0				
		Mild	0	0	0				0.9788
		Moderate	0	0	0				
		Severe	0	0	0				
	Testicular appendage torsion		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 47 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Cardiac disorders			1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Myocarditis		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
		Moderate	0	0	0				
		Severe	0	0	0				
	Wandering pacemaker		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 48 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Immune system disorders			0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9442
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypersensitivity		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
		Moderate	0	0	0				
		Severe	0	0	0				
	Food allergy		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 49 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Musculoskeletal and connective tissue disorders			1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9977
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain in extremity		1 (2.4%)	0	1 (1.6%)				
		Mild	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Arthralgia		0	0	0				
		Mild	0	0	0				0.9788
		Moderate	0	0	0				
		Severe	0	0	0				
	Scoliosis		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 50 of 108

Table 1.18 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=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI][b]	RR [95 %-CI][b] p-value[c]	RD [95 %-CI][b]	Subgroup Interaction p-value
Nervous system disorders			0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9803
		Moderate	0	0	0				
		Severe	0	0	0				
	Headache		0	1 (4.5%)	1 (1.6%)				
		Mild	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9979
		Moderate	0	0	0				
		Severe	0	0	0				
	Dizziness		0	0	0				
		Mild	0	0	0				0.9999
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Congenital, familial and genetic disorders			0	0	0				
		Mild	0	0	0				0.9788
		Moderate	0	0	0				
		Severe	0	0	0				
	Buried penis syndrome		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Supernumerary teeth		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
Endocrine disorders			0	0	0				
		Mild	0	0	0				0.9999
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 52 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Endocrine disorders	Hypothyroidism		0	0	0				
		Mild	0	0	0				0.9788
		Moderate	0	0	0				
		Severe	0	0	0				
	Precocious puberty		0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
Renal and urinary disorders			0	0	0				
		Mild	0	0	0				0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Nocturia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 53 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=42)	Daily rhGH (N=22)	Total (N=64)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Vascular disorders			0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Cyanosis		0	0	0				
		Mild	0	0	0				0.9776
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 54 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Any adverse event			57 (98.3%)	29 (93.5%)	86 (96.6%)			
		Mild	52 (89.7%)	27 (87.1%)	79 (88.8%)	1.2840 [0.3336, 4.9422]	1.0294 [0.8761, 1.2095] 0.7173	0.0256 [-0.1161, 0.1672]
		Moderate	4 (6.9%)	2 (6.5%)	6 (6.7%)	1.0741 [0.1855, 6.2201]	1.0690 [0.2073, 5.5130] 0.9368	0.0044 [-0.1039, 0.1128]
		Severe	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
Investigations			26 (44.8%)	20 (64.5%)	46 (51.7%)			
		Mild	26 (44.8%)	20 (64.5%)	46 (51.7%)	0.4469 [0.1818, 1.0986]	0.6948 [0.4719, 1.0230] 0.0783	-0.1969 [-0.4084, 0.0147]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose increased		13 (22.4%)	14 (45.2%)	27 (30.3%)			
		Mild	13 (22.4%)	14 (45.2%)	27 (30.3%)	0.3508 [0.1372, 0.8969]	0.4963 [0.2680, 0.9191] 0.0270	-0.2275 [-0.4329, -0.0220]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 55 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Insulin-like growth factor increased		12 (20.7%)	2 (6.5%)	14 (15.7%)			
		Mild	12 (20.7%)	2 (6.5%)	14 (15.7%)	3.7826 [0.7890, 18.1349]	3.2069 [0.7659, 13.4278] 0.0805	0.1424 [0.0069, 0.2778]
		Moderate	0	0	0			
		Severe	0	0	0			
	Low density lipoprotein increased		1 (1.7%)	3 (9.7%)	4 (4.5%)			
		Mild	1 (1.7%)	3 (9.7%)	4 (4.5%)	0.1637 [0.0163, 1.6462]	0.1782 [0.0193, 1.6416] 0.0862	-0.0795 [-0.1889, 0.0298]
		Moderate	0	0	0			
		Severe	0	0	0			
	Alanine aminotransferase increased		3 (5.2%)	0	3 (3.4%)			
		Mild	3 (5.2%)	0	3 (3.4%)	3.9730 [0.1987, 79.4228]	3.7966 [0.2024, 71.2280] 0.2002	0.0517 [-0.0053, 0.1087]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 56 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Blood phosphorus increased		3 (5.2%)	0	3 (3.4%)			
		Mild	3 (5.2%)	0	3 (3.4%)	3.9730 [0.1987, 79.4228]	3.7966 [0.2024, 71.2280] 0.2002	0.0517 [-0.0053, 0.1087]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood uric acid increased		2 (3.4%)	1 (3.2%)	3 (3.4%)			
		Mild	2 (3.4%)	1 (3.2%)	3 (3.4%)	1.0714 [0.0933, 12.3057]	1.0690 [0.1009, 11.3272] 0.9561	0.0022 [-0.0757, 0.0802]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cortisol decreased		2 (3.4%)	1 (3.2%)	3 (3.4%)			
		Mild	2 (3.4%)	1 (3.2%)	3 (3.4%)	1.0714 [0.0933, 12.3057]	1.0690 [0.1009, 11.3272] 0.9561	0.0022 [-0.0757, 0.0802]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 57 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Aspartate aminotransferase increased		2 (3.4%)	0	2 (2.2%)			
		Mild	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood alkaline phosphatase increased		1 (1.7%)	1 (3.2%)	2 (2.2%)			
		Mild	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose abnormal		0	2 (6.5%)	2 (2.2%)			
		Mild	0	2 (6.5%)	2 (2.2%)	0.1009 [0.0047, 2.1692]	0.1085 [0.0054, 2.1913] 0.0517	-0.0645 [-0.1510, 0.0220]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 58 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood urea increased		0	2 (6.5%)	2 (2.2%)			
		Mild	0	2 (6.5%)	2 (2.2%)	0.1009 [0.0047, 2.1692]	0.1085 [0.0054, 2.1913] 0.0517	-0.0645 [-0.1510, 0.0220]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eosinophil count increased		1 (1.7%)	1 (3.2%)	2 (2.2%)			
		Mild	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood iron increased		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigation s	Blood triglycerides increased		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardio gram T wave peaked		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardio gram high voltage		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 60 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Hepatic enzyme abnormal		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme increased		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Lipids increased		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Liver function test abnormal		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroid function test abnormal		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroxine free decreased		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 62 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	White blood cell count decreased		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Basophil count increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood cholesterol 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 63 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood lactate dehydrogenase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood potassium increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood pressure 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 64 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Electrocardiogram ST segment abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Haemoglobin decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tri-iodothyronine free increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Infections and infestations			28 (48.3%)	16 (51.6%)	44 (49.4%)			
		Mild	26 (44.8%)	15 (48.4%)	41 (46.1%)	0.8667 [0.3616, 2.0771]	0.9264 [0.5835, 1.4709] 0.7496	-0.0356 [-0.2531, 0.1820]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 65 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations		Moderate	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]
		Severe	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
	Upper respiratory tract infection		21 (36.2%)	11 (35.5%)	32 (36.0%)			
		Mild	21 (36.2%)	10 (32.3%)	31 (34.8%)	1.1919 [0.4731, 3.0029]	1.1224 [0.6075, 2.0739] 0.7111	0.0395 [-0.1664, 0.2453]
		Moderate	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Severe	0	0	0			
	Respiratory tract infection		4 (6.9%)	2 (6.5%)	6 (6.7%)			
		Mild	4 (6.9%)	2 (6.5%)	6 (6.7%)	1.0741 [0.1855, 6.2201]	1.0690 [0.2073, 5.5130] 0.9368	0.0044 [-0.1039, 0.1128]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 66 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Tonsillitis		3 (5.2%)	2 (6.5%)	5 (5.6%)			
		Mild	3 (5.2%)	2 (6.5%)	5 (5.6%)	0.7909 [0.1250, 5.0043]	0.8017 [0.1414, 4.5460] 0.8039	-0.0128 [-0.1164, 0.0908]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasopharyngitis		1 (1.7%)	2 (6.5%)	3 (3.4%)			
		Mild	1 (1.7%)	2 (6.5%)	3 (3.4%)	0.2544 [0.0221, 2.9236]	0.2672 [0.0252, 2.8318] 0.2417	-0.0473 [-0.1400, 0.0455]
		Moderate	0	0	0			
		Severe	0	0	0			
	Rhinitis		2 (3.4%)	1 (3.2%)	3 (3.4%)			
		Mild	2 (3.4%)	1 (3.2%)	3 (3.4%)	1.0714 [0.0933, 12.3057]	1.0690 [0.1009, 11.3272] 0.9561	0.0022 [-0.0757, 0.0802]
		Moderate	0	0	0			
		Severe	0	0	0			
	Periodontitis		2 (3.4%)	0	2 (2.2%)			
		Mild	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Abscess limb		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Bronchitis		1 (1.7%)	0	1 (1.1%)			
		Mild	0	0	0			
		Moderate	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Severe	0	0	0			
	Chronic sinusitis		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Chronic tonsillitis		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Gastroenteritis		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hordeolum		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Influenza		1 (1.7%)	0	1 (1.1%)			
		Mild	0	0	0			
		Moderate	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Severe	0	0	0			
	Myringitis		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Oral herpes		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis media		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngitis		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pneumonia		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 70 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Sinusitis		0	1 (3.2%)	1 (1.1%)			
		Mild	0	0	0			
		Moderate	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Severe	0	0	0			
	Tonsillitis bacterial		1 (1.7%)	0	1 (1.1%)			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
	Tracheitis		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Urinary tract infection		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 71 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Varicella		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Bacterial infection		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			
	Folliculitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 72 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Gastroenteritis viral		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastrointestinal bacterial infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hand-foot-and-mouth disease		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpangina		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 73 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Herpes virus infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Infectious mononucleosis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Laryngitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Mumps		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 74 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Peritonsillar abscess		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			
	Sinobronchitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Subcutaneous abscess		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 75 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders			15 (25.9%)	8 (25.8%)	23 (25.8%)			
		Mild	15 (25.9%)	7 (22.6%)	22 (24.7%)	1.1960 [0.4284, 3.3393]	1.1453 [0.5229, 2.5086] 0.7339	0.0328 [-0.1526, 0.2182]
		Moderate	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Severe	0	0	0			
	Cough		12 (20.7%)	5 (16.1%)	17 (19.1%)			
		Mild	12 (20.7%)	4 (12.9%)	16 (18.0%)	1.7609 [0.5161, 6.0081]	1.6034 [0.5644, 4.5556] 0.3648	0.0779 [-0.0796, 0.2353]
		Moderate	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Severe	0	0	0			
	Rhinorrhoea		1 (1.7%)	3 (9.7%)	4 (4.5%)			
		Mild	1 (1.7%)	3 (9.7%)	4 (4.5%)	0.1637 [0.0163, 1.6462]	0.1782 [0.0193, 1.6416] 0.0862	-0.0795 [-0.1889, 0.0298]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 76 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic		1 (1.7%)	1 (3.2%)	2 (2.2%)			
		Mild	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]
		Moderate	0	0	0			
		Severe	0	0	0			
	Asthma		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal congestion		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Adenoidal hypertrophy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Allergic cough		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal obstruction		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 78 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Productive cough		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			
General disorders and administratio n site conditions			11 (19.0%)	9 (29.0%)	20 (22.5%)			
		Mild	10 (17.2%)	9 (29.0%)	19 (21.3%)	0.5093 [0.1814, 1.4297]	0.5939 [0.2701, 1.3058] 0.1984	-0.1179 [-0.3049, 0.0691]
		Moderate	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 79 of 108

Anhang 4-H   Seite 148 von 682

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Pyrexia		9 (15.5%)	5 (16.1%)	14 (15.7%)			
		Mild	9 (15.5%)	5 (16.1%)	14 (15.7%)	0.9551 [0.2899, 3.1463]	0.9621 [0.3530, 2.6217] 0.9401	-0.0061 [-0.1656, 0.1534]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site pain		2 (3.4%)	0	2 (2.2%)			
		Mild	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site pruritus		1 (1.7%)	1 (3.2%)	2 (2.2%)			
		Mild	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 80 of 108

Table 1.18 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=58) | Daily rhGH (N=31) | Total (N=89) | Lonapegsomatropin vs. Daily rhGH [a] | | |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site bruising		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site erythema		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site reaction		1 (1.7%)	0	1 (1.1%)			
		Mild	0	0	0			
		Moderate	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 81 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site swelling		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Peripheral swelling		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administratio n site conditions	Injection site haemorrhage		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Gastrointesti nal disorders			12 (20.7%)	6 (19.4%)	18 (20.2%)			
		Mild	12 (20.7%)	6 (19.4%)	18 (20.2%)	1.0870 [0.3639, 3.2469]	1.0690 [0.4444, 2.5710] 0.8819	0.0133 [-0.1605, 0.1872]
		Moderate	0	0	0			
		Severe	0	0	0			
	Diarrhoea		3 (5.2%)	3 (9.7%)	6 (6.7%)			
		Mild	3 (5.2%)	3 (9.7%)	6 (6.7%)	0.5091 [0.0964, 2.6875]	0.5345 [0.1146, 2.4925] 0.4220	-0.0451 [-0.1637, 0.0736]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dyspepsia		2 (3.4%)	1 (3.2%)	3 (3.4%)			
		Mild	2 (3.4%)	1 (3.2%)	3 (3.4%)	1.0714 [0.0933, 12.3057]	1.0690 [0.1009, 11.3272] 0.9561	0.0022 [-0.0757, 0.0802]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 83 of 108

Anhang 4-H   Seite 152 von 682

Table 1.18 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointesti nal disorders	Abdominal pain upper		2 (3.4%)	0	2 (2.2%)			
		Mild	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
		Moderate	0	0	0			
		Severe	0	0	0			
	Toothache		1 (1.7%)	1 (3.2%)	2 (2.2%)			
		Mild	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal distension		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal pain		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 84 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Gastrointestinal disorder		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nausea		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Noninfective gingivitis		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Vomiting		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 85 of 108

Table 1.18 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Gastrointesti nal disorders	Constipation		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Enteritis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Metabolism and nutrition disorders			5 (8.6%)	7 (22.6%)	12 (13.5%)			
		Mild	5 (8.6%)	7 (22.6%)	12 (13.5%)	0.3235 [0.0931, 1.1231]	0.3818 [0.1321, 1.1037] 0.0677	-0.1396 [-0.3036, 0.0244]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypertriglyce ridaemia		4 (6.9%)	2 (6.5%)	6 (6.7%)			
		Mild	4 (6.9%)	2 (6.5%)	6 (6.7%)	1.0741 [0.1855, 6.2201]	1.0690 [0.2073, 5.5130] 0.9368	0.0044 [-0.1039, 0.1128]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58) | Daily rhGH (N=31) | Total (N=89) | Lonapegsomatropin vs. Daily rhGH [a] | | |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Hypercholeste rolaemia		1 (1.7%)	2 (6.5%)	3 (3.4%)			
		Mild	1 (1.7%)	2 (6.5%)	3 (3.4%)	0.2544 [0.0221, 2.9236]	0.2672 [0.0252, 2.8318] 0.2417	-0.0473 [-0.1400, 0.0455]
		Moderate	0	0	0			
		Severe	0	0	0			
	Calcium deficiency		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Decreased appetite		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 87 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Hyperglycaemia		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperlipidaemia		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperuricaemia		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

			TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Eye disorders			8 (13.8%)	2 (6.5%)	10 (11.2%)			
		Mild	7 (12.1%)	2 (6.5%)	9 (10.1%)	1.9902 [0.3875, 10.2213]	1.8707 [0.4134, 8.4660] 0.4050	0.0562 [-0.0643, 0.1766]
		Moderate	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Severe	0	0	0			
	Refraction disorder		3 (5.2%)	1 (3.2%)	4 (4.5%)			
		Mild	3 (5.2%)	1 (3.2%)	4 (4.5%)	1.6364 [0.1630, 16.4275]	1.6034 [0.1740, 14.7748] 0.6745	0.0195 [-0.0649, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			
	Papilloedema		1 (1.7%)	1 (3.2%)	2 (2.2%)			
		Mild	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 89 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Corneal epithelium defect		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye pain		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye swelling		1 (1.7%)	0	1 (1.1%)			
		Mild	0	0	0			
		Moderate	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Severe	0	0	0			
	Vitreous opacities		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Xerophthalmia		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		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			
	Myopia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vernal keratoconjunctivitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 91 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Nervous system disorders			2 (3.4%)	5 (16.1%)	7 (7.9%)			
		Mild	2 (3.4%)	5 (16.1%)	7 (7.9%)	0.1857 [0.0338, 1.0212]	0.2138 [0.0440, 1.0388] 0.0353	-0.1268 [-0.2645, 0.0109]
		Moderate	0	0	0			
		Severe	0	0	0			
	Headache		0	4 (12.9%)	4 (4.5%)			
		Mild	0	4 (12.9%)	4 (4.5%)	0.0522 [0.0027, 1.0046]	0.0603 [0.0033, 1.0842] 0.0054	-0.1290 [-0.2470, -0.0110]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dizziness		2 (3.4%)	1 (3.2%)	3 (3.4%)			
		Mild	2 (3.4%)	1 (3.2%)	3 (3.4%)	1.0714 [0.0933, 12.3057]	1.0690 [0.1009, 11.3272] 0.9561	0.0022 [-0.0757, 0.0802]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 92 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders			5 (8.6%)	2 (6.5%)	7 (7.9%)			
		Mild	5 (8.6%)	2 (6.5%)	7 (7.9%)	1.3679 [0.2496, 7.4967]	1.3362 [0.2750, 6.4923] 0.7188	0.0217 [-0.0910, 0.1344]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis allergic		1 (1.7%)	1 (3.2%)	2 (2.2%)			
		Mild	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis contact		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 93 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eczema		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Rash		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 94 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Urticaria papular		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria chronic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Blood and lymphatic system disorders			3 (5.2%)	1 (3.2%)	4 (4.5%)			
		Mild	2 (3.4%)	1 (3.2%)	3 (3.4%)	1.0714 [0.0933, 12.3057]	1.0690 [0.1009, 11.3272] 0.9561	0.0022 [-0.0757, 0.0802]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 95 of 108

Table 1.18 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

						Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders		Moderate	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Severe	0	0	0			
	Anaemia		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Granulocytope nia		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypochromic anaemia		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders	Thymus disorder		1 (1.7%)	0	1 (1.1%)			
		Mild	0	0	0			
		Moderate	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Severe	0	0	0			
	Lymphadenitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Injury, poisoning and procedural complications			4 (6.9%)	0	4 (4.5%)			
		Mild	4 (6.9%)	0	4 (4.5%)	5.2018 [0.2710, 99.8333]	4.8814 [0.2713, 87.8214] 0.1368	0.0690 [0.0038, 0.1342]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 97 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications	Head injury		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Joint injury		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Ligament sprain		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
| | | | | | | OR | RR [95 %-CI] [b] | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=58)	Daily rhGH (N=31)	Total (N=89)	[95 %-CI] [b]	p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications	Skin laceration		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Animal scratch		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 99 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Musculoskeletal and connective tissue disorders			4 (6.9%)	0	4 (4.5%)			
		Mild	4 (6.9%)	0	4 (4.5%)	5.2018 [0.2710, 99.8333]	4.8814 [0.2713, 87.8214] 0.1368	0.0690 [0.0038, 0.1342]
		Moderate	0	0	0			
		Severe	0	0	0			
	Arthralgia		2 (3.4%)	0	2 (2.2%)			
		Mild	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain in extremity		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Musculoskeletal and connective tissue disorders	Scoliosis		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
Endocrine disorders			2 (3.4%)	1 (3.2%)	3 (3.4%)			
		Mild	2 (3.4%)	1 (3.2%)	3 (3.4%)	1.0714 [0.0933, 12.3057]	1.0690 [0.1009, 11.3272] 0.9561	0.0022 [-0.0757, 0.0802]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypothyroidism		2 (3.4%)	0	2 (2.2%)			
		Mild	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 101 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Endocrine disorders	Precocious puberty		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
Reproductive system and breast disorders			3 (5.2%)	0	3 (3.4%)			
		Mild	3 (5.2%)	0	3 (3.4%)	3.9730 [0.1987, 79.4228]	3.7966 [0.2024, 71.2280] 0.2002	0.0517 [-0.0053, 0.1087]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gynaecomastia		2 (3.4%)	0	2 (2.2%)			
		Mild	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 102 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Reproductive system and breast disorders	Testicular appendage torsion		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Balanoposthitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pelvic fluid collection		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.

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Congenital, familial and genetic disorders			2 (3.4%)	0	2 (2.2%)			
		Mild	2 (3.4%)	0	2 (2.2%)	2.7876 [0.1297, 59.8994]	2.7119 [0.1342, 54.7816] 0.2984	0.0345 [-0.0125, 0.0814]
		Moderate	0	0	0			
		Severe	0	0	0			
	Buried penis syndrome		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Supernumerary teeth		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | |
| | | | TransCon hGH (N=58) | Daily rhGH (N=31) | Total (N=89) | OR [95 %-CI] [b] | RR [95 %-CI] [b] p-value[c] | RD [95 %-CI] [b] |
System Organ Class	Preferred Term	Severity						
Cardiac disorders			1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Wandering pacemaker		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Myocarditis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Immune system disorders			1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 105 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Immune system disorders	Food allergy		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypersensitivity		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Renal and urinary disorders			0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 0.0299]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nocturia		0	1 (3.2%)	1 (1.1%)			
		Mild	0	1 (3.2%)	1 (1.1%)	0.1738 [0.0069, 4.3951]	0.1808 [0.0076, 4.3109] 0.1714	-0.0323 [-0.0945, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Vascular disorders			1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cyanosis		1 (1.7%)	0	1 (1.1%)			
		Mild	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]
		Moderate	0	0	0			
		Severe	0	0	0			
Ear and labyrinth disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cerumen impaction		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 107 of 108

Table 1.18 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Ear and labyrinth disorders	Motion sickness		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 108 of 108

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Any adverse event			87 (100.0%)	43 (95.6%)	130 (98.5%)				
		Mild	79 (90.8%)	39 (86.7%)	118 (89.4%)	1.5216 [0.4931, 4.6948]	1.0478 [0.9177, 1.1964] 0.4664	0.0415 [-0.0749, 0.1578]	0.4007
		Moderate	6 (6.9%)	4 (8.9%)	10 (7.6%)	0.7584 [0.2025, 2.8401]	0.7752 [0.2306, 2.6056] 0.6830	-0.0200 [-0.1187, 0.0787]	0.9723
		Severe	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795
Infections and infestations			54 (62.1%)	29 (64.4%)	83 (62.9%)				
		Mild	51 (58.6%)	26 (57.8%)	77 (58.3%)	1.0335 [0.4841, 2.2066]	1.0128 [0.7548, 1.3592] 0.9328	0.0074 [-0.1634, 0.1782]	0.1315
		Moderate	1 (1.1%)	3 (6.7%)	4 (3.0%)	0.1568 [0.0153, 1.6035]	0.1712 [0.0185, 1.5820] 0.0793	-0.0553 [-0.1313, 0.0206]	0.9652
		Severe	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795

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

v9.4 26MAY2023:14:13 Page 1 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Upper respiratory tract infection		39 (44.8%)	25 (55.6%)	64 (48.5%)				
		Mild	39 (44.8%)	22 (48.9%)	61 (46.2%)	0.8343 [0.3938, 1.7674]	0.9149 [0.6361, 1.3159] 0.6395	-0.0416 [-0.2142, 0.1310]	0.4121
		Moderate	0	3 (6.7%)	3 (2.3%)	0.1238 [0.0133, 1.1561]	0.1343 [0.0153, 1.1802] 0.0152	-0.0667 [-0.1397, 0.0062]	0.9725
		Severe	0	0	0				
	Bronchitis		8 (9.2%)	2 (4.4%)	10 (7.6%)				
		Mild	6 (6.9%)	2 (4.4%)	8 (6.1%)	1.6364 [0.2989, 8.9595]	1.5385 [0.3410, 6.9418] 0.5707	0.0240 [-0.0532, 0.1012]	0.9760
		Moderate	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Severe	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
	Tonsillitis		6 (6.9%)	4 (8.9%)	10 (7.6%)				
		Mild	6 (6.9%)	4 (8.9%)	10 (7.6%)	0.7584 [0.2025, 2.8401]	0.7752 [0.2306, 2.6056] 0.6830	-0.0200 [-0.1187, 0.0787]	0.9995
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 2 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Respiratory tract infection		5 (5.7%)	2 (4.4%)	7 (5.3%)				
		Mild	5 (5.7%)	2 (4.4%)	7 (5.3%)	1.3130 [0.2456, 7.0212]	1.2960 [0.2616, 6.4217] 0.7503	0.0132 [-0.0646, 0.0909]	0.9674
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasopharyngitis		2 (2.3%)	3 (6.7%)	5 (3.8%)				
		Mild	2 (2.3%)	2 (4.4%)	4 (3.0%)	0.5079 [0.0695, 3.7099]	0.5182 [0.0749, 3.5830] 0.4996	-0.0214 [-0.0893, 0.0466]	0.9744
		Moderate	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Severe	0	0	0				
	Pneumonia		2 (2.3%)	2 (4.4%)	4 (3.0%)				
		Mild	2 (2.3%)	2 (4.4%)	4 (3.0%)	0.5014 [0.0674, 3.7307]	0.5142 [0.0749, 3.5294] 0.4933	-0.0216 [-0.0894, 0.0462]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Herpangina		3 (3.4%)	0	3 (2.3%)				
		Mild	3 (3.4%)	0	3 (2.3%)	3.9315 [0.1934, 79.9326]	3.6750 [0.1991, 67.8493] 0.2068	0.0343 [-0.0040, 0.0725]	0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis media		2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0311 [0.0931, 11.4142]	1.0311 [0.0927, 11.4660] 0.9800	0.0007 [-0.0532, 0.0546]	0.9999
		Moderate	0	0	0				
		Severe	0	0	0				
	Periodontitis		3 (3.4%)	0	3 (2.3%)				
		Mild	3 (3.4%)	0	3 (2.3%)	2.1236 [0.2279, 19.7866]	2.0717 [0.2355, 18.2204] 0.2103	0.0345 [-0.0038, 0.0729]	0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
	Rhinitis		2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0435 [0.0900, 12.1002]	1.0417 [0.0992, 10.9364] 0.9730	0.0009 [-0.0519, 0.0538]	0.9999
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 4 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Gastroenteritis		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5155 [0.0320, 8.3000]	0.5155 [0.0319, 8.3314] 0.6346	-0.0107 [-0.0596, 0.0381]	0.9746
		Moderate	0	0	0				
		Severe	0	0	0				
	Hand-foot-and-mouth disease		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7333 [0.1252, 59.6946]	2.6250 [0.1320, 52.2037] 0.3070	0.0229 [-0.0085, 0.0543]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Laryngitis		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0296, 8.4388]	0.5128 [0.0338, 7.7761] 0.6275	-0.0109 [-0.0590, 0.0373]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 5 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Oral herpes		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5155 [0.0320, 8.3000]	0.5155 [0.0319, 8.3314] 0.6346	-0.0107 [-0.0596, 0.0381]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis media acute		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0296, 8.4388]	0.5128 [0.0338, 7.7761] 0.6275	-0.0109 [-0.0590, 0.0373]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Pharyngitis		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0296, 8.4388]	0.5128 [0.0338, 7.7761] 0.6275	-0.0109 [-0.0590, 0.0373]	0.9746
		Moderate	0	0	0				
		Severe	0	0	0				
	Sinusitis		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	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.

v9.4 26MAY2023:14:13 Page 6 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Sinusitis	Moderate	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Severe	0	0	0				
	Varicella		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5181 [0.0326, 8.2257]	0.5181 [0.0328, 8.1946] 0.6346	-0.0107 [-0.0597, 0.0382]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Abscess limb		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Bacterial infection		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 7 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Chronic tonsillitis		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Conjunctivitis		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9470
		Moderate	0	0	0				
		Severe	0	0	0				
	Folliculitis		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 8 of 105

Anhang 4-H   Seite 185 von 682

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Gastroenteritis viral		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal bacterial infection		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Herpes virus infection		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Hordeolum		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Infectious mononucleosis		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Mumps		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Myringitis		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 10 of 105

Table 1.19 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=87) | Daily rhGH (N=45) | Total (N=132) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Peritonsillar abscess		0	1 (2.2%)	1 (0.8%)				
		Mild	0	0	0				
		Moderate	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Severe	0	0	0				
	Pulpitis dental		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Sinobronchitis		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Subcutaneous abscess		1 (1.1%)	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Subcutaneous abscess	Moderate	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Severe	0	0	0				
	Tonsillitis bacterial		1 (1.1%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
	Tracheitis		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Chronic sinusitis		0	0	0				
		Mild	0	0	0				0.9710
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 12 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Influenza		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9710
		Severe	0	0	0				
	Urinary tract infection		0	0	0				
		Mild	0	0	0				0.9773
		Moderate	0	0	0				
		Severe	0	0	0				
Investigations			47 (54.0%)	25 (55.6%)	72 (54.5%)				
		Mild	47 (54.0%)	25 (55.6%)	72 (54.5%)	0.9411 [0.4607, 1.9226]	0.9722 [0.6990, 1.3523] 0.8670	-0.0154 [-0.1967, 0.1659]	0.2695
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose increased		17 (19.5%)	14 (31.1%)	31 (23.5%)				
		Mild	17 (19.5%)	14 (31.1%)	31 (23.5%)	0.5240 [0.2248, 1.2213]	0.6300 [0.3478, 1.1411] 0.1336	-0.1150 [-0.2705, 0.0404]	0.9733
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 13 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Insulin-like growth factor increased		26 (29.9%)	2 (4.4%)	28 (21.2%)				
		Mild	26 (29.9%)	2 (4.4%)	28 (21.2%)	9.2969 [2.1027, 41.1054]	6.7080 [1.6692, 26.9573] 0.0006	0.2538 [0.1406, 0.3669]	0.3155
		Moderate	0	0	0				
		Severe	0	0	0				
	Low density lipoprotein increased		4 (4.6%)	4 (8.9%)	8 (6.1%)				
		Mild	4 (4.6%)	4 (8.9%)	8 (6.1%)	0.4987 [0.1198, 2.0760]	0.5162 [0.1335, 1.9963] 0.3303	-0.0430 [-0.1376, 0.0517]	0.9981
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood alkaline phosphatase increased		3 (3.4%)	4 (8.9%)	7 (5.3%)				
		Mild	3 (3.4%)	4 (8.9%)	7 (5.3%)	0.3584 [0.0758, 1.6957]	0.3864 [0.0915, 1.6317] 0.1840	-0.0546 [-0.1456, 0.0364]	0.9975
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood phosphorus increased		4 (4.6%)	1 (2.2%)	5 (3.8%)				
		Mild	4 (4.6%)	1 (2.2%)	5 (3.8%)	2.0952 [0.2314, 18.9719]	2.0671 [0.2361, 18.0969] 0.5007	0.0238 [-0.0383, 0.0859]	0.9984
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood uric acid increased		3 (3.4%)	2 (4.4%)	5 (3.8%)				
		Mild	3 (3.4%)	2 (4.4%)	5 (3.8%)	0.7688 [0.1239, 4.7693]	0.7765 [0.1346, 4.4797] 0.7785	-0.0099 [-0.0814, 0.0615]	0.9994
		Moderate	0	0	0				
		Severe	0	0	0				
	Alanine aminotransferase increased		3 (3.4%)	1 (2.2%)	4 (3.0%)				
		Mild	3 (3.4%)	1 (2.2%)	4 (3.0%)	1.5543 [0.1632, 14.8049]	1.5543 [0.1629, 14.8324] 0.6963	0.0124 [-0.0463, 0.0710]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 15 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Blood iron increased		2 (2.3%)	2 (4.4%)	4 (3.0%)				
		Mild	2 (2.3%)	2 (4.4%)	4 (3.0%)	0.5027 [0.0687, 3.6764]	0.5155 [0.0757, 3.5119] 0.4933	-0.0216 [-0.0895, 0.0463]	0.9987
		Moderate	0	0	0				
		Severe	0	0	0				
	Eosinophil count increased		3 (3.4%)	1 (2.2%)	4 (3.0%)				
		Mild	3 (3.4%)	1 (2.2%)	4 (3.0%)	1.5636 [0.1596, 15.3193]	1.5519 [0.1635, 14.7348] 0.6996	0.0122 [-0.0457, 0.0702]	0.9991
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood triglycerides increased		2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0317 [0.0909, 11.7108]	1.0309 [0.0968, 10.9833] 0.9800	0.0007 [-0.0526, 0.0540]	0.9999
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Aspartate aminotransferase increased		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7419 [0.1267, 59.3349]	2.6531 [0.1322, 53.2292] 0.3041	0.0231 [-0.0085, 0.0547]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose abnormal		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5155 [0.0320, 8.3000]	0.5155 [0.0319, 8.3314] 0.6346	-0.0107 [-0.0596, 0.0381]	0.9746
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood urea increased		0	2 (4.4%)	2 (1.5%)				
		Mild	0	2 (4.4%)	2 (1.5%)	0.0969 [0.0045, 2.1003]	0.1061 [0.0053, 2.1292] 0.0485	-0.0443 [-0.1045, 0.0158]	0.9775
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 17 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Cortisol decreased		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9726
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram T wave peaked		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Tri-iodothyronine free increased		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0296, 8.4388]	0.5128 [0.0338, 7.7761] 0.6275	-0.0109 [-0.0590, 0.0373]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Basophil count increased		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood cholesterol increased		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood lactate dehydrogenase increased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 19 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood potassium increased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood pressure increased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood thyroid stimulating hormone increased		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Electrocardiogram ST segment abnormal		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram high voltage		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Haemoglobin decreased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 21 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Hepatic enzyme abnormal		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Hepatic enzyme increased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Lipids increased		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 22 of 105

Table 1.19 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=87) | Daily rhGH (N=45) | Total (N=132) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Thyroid function test abnormal		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Thyroxine free decreased		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	White blood cell count decreased		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 23 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Liver function test abnormal		0	0	0				
		Mild	0	0	0				0.9773
		Moderate	0	0	0				
		Severe	0	0	0				
Respiratory, thoracic and mediastinal disorders			29 (33.3%)	13 (28.9%)	42 (31.8%)				
		Mild	29 (33.3%)	11 (24.4%)	40 (30.3%)	1.5311 [0.6845, 3.4247]	1.3623 [0.7484, 2.4796] 0.2952	0.0885 [-0.0729, 0.2499]	0.9671
		Moderate	0	2 (4.4%)	2 (1.5%)	0.1665 [0.0168, 1.6476]	0.1759 [0.0188, 1.6445] 0.0492	-0.0445 [-0.1047, 0.0158]	0.9775
		Severe	0	0	0				
	Cough		23 (26.4%)	8 (17.8%)	31 (23.5%)				
		Mild	23 (26.4%)	6 (13.3%)	29 (22.0%)	2.2987 [0.8695, 6.0765]	1.9807 [0.8639, 4.5412] 0.0860	0.1307 [-0.0063, 0.2677]	0.9710

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Cough	Moderate	0	2 (4.4%)	2 (1.5%)	0.1665 [0.0168, 1.6476]	0.1759 [0.0188, 1.6445] 0.0492	−0.0445 [−0.1047, 0.0158]	0.9775
		Severe	0	0	0				
	Rhinorrhoea		4 (4.6%)	4 (8.9%)	8 (6.1%)				
		Mild	4 (4.6%)	4 (8.9%)	8 (6.1%)	0.4987 [0.1198, 2.0760]	0.5162 [0.1335, 1.9963] 0.3303	−0.0430 [−0.1376, 0.0517]	0.9981
		Moderate	0	0	0				
		Severe	0	0	0				
	Rhinitis allergic		3 (3.4%)	2 (4.4%)	5 (3.8%)				
		Mild	3 (3.4%)	2 (4.4%)	5 (3.8%)	0.7654 [0.1229, 4.7690]	0.7739 [0.1342, 4.4620] 0.7755	−0.0101 [−0.0814, 0.0612]	0.9994
		Moderate	0	0	0				
		Severe	0	0	0				
	Asthma		2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0317 [0.0909, 11.7108]	1.0309 [0.0968, 10.9833] 0.9800	0.0007 [−0.0526, 0.0540]	0.9999
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Allergic cough		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal congestion		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Oropharyngeal pain		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Productive cough		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 27 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
General disorders and administration site conditions			19 (21.8%)	11 (24.4%)	30 (22.7%)				
		Mild	17 (19.5%)	10 (22.2%)	27 (20.5%)	0.8511 [0.3535, 2.0492]	0.8798 [0.4391, 1.7628] 0.7204	-0.0267 [-0.1742, 0.1208]	0.3812
		Moderate	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0317 [0.0909, 11.7108]	1.0309 [0.0968, 10.9833] 0.9800	0.0007 [-0.0526, 0.0540]	0.9999
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Pyrexia		15 (17.2%)	8 (17.8%)	23 (17.4%)				
		Mild	14 (16.1%)	7 (15.6%)	21 (15.9%)	1.0425 [0.3874, 2.8050]	1.0356 [0.4505, 2.3805] 0.9348	0.0055 [-0.1253, 0.1364]	0.9767
		Moderate	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0296, 8.4388]	0.5128 [0.0338, 7.7761] 0.6275	-0.0109 [-0.0590, 0.0373]	0.9985
		Severe	0	0	0				
	Injection site pain		3 (3.4%)	0	3 (2.3%)				
		Mild	3 (3.4%)	0	3 (2.3%)	2.1236 [0.2279, 19.7866]	2.0717 [0.2355, 18.2204] 0.2103	0.0345 [-0.0038, 0.0729]	0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site pruritus		2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0371 [0.0915, 11.7510]	1.0364 [0.0959, 11.1985] 0.9767	0.0008 [-0.0526, 0.0542]	0.9999
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 29 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site erythema		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5181 [0.0326, 8.2257]	0.5181 [0.0328, 8.1946] 0.6346	-0.0107 [-0.0597, 0.0382]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site reaction		2 (2.3%)	0	2 (1.5%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Severe	0	0	0				
	Injection site bruising		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site haemorrhage		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Peripheral swelling		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site swelling		0	0	0				
		Mild	0	0	0				0.9773
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain		0	0	0				
		Mild	0	0	0				0.9773
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Gastrointestinal disorders			14 (16.1%)	11 (24.4%)	25 (18.9%)				
		Mild	14 (16.1%)	11 (24.4%)	25 (18.9%)	0.5937 [0.2442, 1.4430]	0.6589 [0.3262, 1.3307] 0.2496	-0.0834 [-0.2309, 0.0641]	0.3433
		Moderate	0	0	0				
		Severe	0	0	0				
	Diarrhoea		5 (5.7%)	5 (11.1%)	10 (7.6%)				
		Mild	5 (5.7%)	5 (11.1%)	10 (7.6%)	0.4880 [0.1336, 1.7826]	0.5166 [0.1574, 1.6957] 0.2725	-0.0537 [-0.1578, 0.0504]	0.9712
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyspepsia		2 (2.3%)	2 (4.4%)	4 (3.0%)				
		Mild	2 (2.3%)	2 (4.4%)	4 (3.0%)	0.5093 [0.0694, 3.7360]	0.5195 [0.0757, 3.5651] 0.4996	-0.0214 [-0.0895, 0.0467]	0.9987
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal pain upper		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7419 [0.1267, 59.3349]	2.6531 [0.1322, 53.2292] 0.3041	0.0231 [-0.0085, 0.0547]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 32 of 105

Anhang 4-H   Seite 209 von 682

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Gastrointestinal disorders	Enteritis		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0296, 8.4388]	0.5128 [0.0338, 7.7761] 0.6275	-0.0109 [-0.0590, 0.0373]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal disorder		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal distension		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Constipation		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Nausea		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Noninfective gingivitis		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Toothache		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9515
		Moderate	0	0	0				
		Severe	0	0	0				
	Vomiting		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Gastrointestinal disorders	Abdominal pain		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
Metabolism and nutrition disorders			12 (13.8%)	8 (17.8%)	20 (15.2%)				
		Mild	12 (13.8%)	8 (17.8%)	20 (15.2%)	0.7474 [0.2858, 1.9548]	0.7761 [0.3370, 1.7876] 0.5489	-0.0397 [-0.1749, 0.0954]	0.9992
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypertriglyceridaemia		7 (8.0%)	2 (4.4%)	9 (6.8%)				
		Mild	7 (8.0%)	2 (4.4%)	9 (6.8%)	1.8891 [0.3737, 9.5482]	1.8150 [0.3928, 8.3852] 0.4376	0.0361 [-0.0467, 0.1190]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders	Hypercholeste rolaemia		3 (3.4%)	3 (6.7%)	6 (4.5%)				
		Mild	3 (3.4%)	3 (6.7%)	6 (4.5%)	0.5009 [0.0971, 2.5830]	0.5164 [0.1079, 2.4710] 0.4030	-0.0322 [-0.1147, 0.0503]	0.9984
		Moderate	0	0	0				
		Severe	0	0	0				
	Decreased appetite		2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0311 [0.0931, 11.4142]	1.0311 [0.0927, 11.4660] 0.9800	0.0007 [-0.0532, 0.0546]	0.9999
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperuricaemi a		2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0317 [0.0909, 11.7108]	1.0309 [0.0968, 10.9833] 0.9800	0.0007 [-0.0526, 0.0540]	0.9999
		Moderate	0	0	0				
		Severe	0	0	0				

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

v9.4 26MAY2023:14:13 Page 36 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders	Calcium deficiency		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperglycaemia		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperlipidaemia		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 37 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders			10 (11.5%)	3 (6.7%)	13 (9.8%)				
		Mild	9 (10.3%)	3 (6.7%)	12 (9.1%)	1.6279 [0.4162, 6.3678]	1.5562 [0.4457, 5.4337] 0.4826	0.0371 [-0.0595, 0.1336]	0.9736
		Moderate	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Severe	0	0	0				
	Refraction disorder		3 (3.4%)	2 (4.4%)	5 (3.8%)				
		Mild	3 (3.4%)	2 (4.4%)	5 (3.8%)	0.7721 [0.1247, 4.7810]	0.7792 [0.1350, 4.4975] 0.7801	-0.0098 [-0.0814, 0.0618]	0.9994
		Moderate	0	0	0				
		Severe	0	0	0				
	Papilloedema		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5106 [0.0306, 8.5249]	0.5208 [0.0340, 7.9805] 0.6364	-0.0106 [-0.0589, 0.0376]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 38 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Eye disorders	Conjunctivitis allergic		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Corneal epithelium defect		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye pain		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye swelling		1 (1.1%)	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 39 of 105

Table 1.19 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=87) | Daily rhGH (N=45) | Total (N=132) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Eye disorders	Eye swelling	Moderate	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Severe	0	0	0				
	Myopia		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Vitreous opacities		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Xerophthalmia		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 40 of 105

Table 1.19 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=87) | Daily rhGH (N=45) | Total (N=132) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Eye disorders	Vernal keratoconjunctivitis		0	0	0				
		Mild	0	0	0				0.9773
		Moderate	0	0	0				
		Severe	0	0	0				
Skin and subcutaneous tissue disorders			7 (8.0%)	2 (4.4%)	9 (6.8%)				
		Mild	7 (8.0%)	2 (4.4%)	9 (6.8%)	1.8665 [0.3746, 9.3000]	1.8123 [0.3878, 8.4707] 0.4399	0.0360 [-0.0475, 0.1196]	0.9704
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis allergic		2 (2.3%)	1 (2.2%)	3 (2.3%)				
		Mild	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0371 [0.0915, 11.7510]	1.0364 [0.0959, 11.1985] 0.9767	0.0008 [-0.0526, 0.0542]	0.9999
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 41 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Urticaria papular		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyshidrotic eczema		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Eczema		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9966
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Rash		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9938
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria chronic		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Skin and subcutaneous tissue disorders	Dermatitis		0	0	0				
		Mild	0	0	0				0.9710
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis contact		0	0	0				
		Mild	0	0	0				0.9710
		Moderate	0	0	0				
		Severe	0	0	0				
Blood and lymphatic system disorders			6 (6.9%)	2 (4.4%)	8 (6.1%)				
		Mild	5 (5.7%)	2 (4.4%)	7 (5.3%)	1.3091 [0.2434, 7.0400]	1.2907 [0.2608, 6.3867] 0.7548	0.0129 [-0.0646, 0.0904]	0.9993
		Moderate	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 44 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Blood and lymphatic system disorders	Anaemia		0	2 (4.4%)	2 (1.5%)				
		Mild	0	2 (4.4%)	2 (1.5%)	0.1665 [0.0168, 1.6476]	0.1759 [0.0188, 1.6445] 0.0492	-0.0445 [-0.1047, 0.0158]	0.9775
		Moderate	0	0	0				
		Severe	0	0	0				
	Granulocytopenia		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Lymphadenitis		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7333 [0.1252, 59.6946]	2.6250 [0.1320, 52.2037] 0.3070	0.0229 [-0.0085, 0.0543]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				

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

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Blood and lymphatic system disorders	Hypochromic anaemia		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Thymus disorder		1 (1.1%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Severe	0	0	0				
Injury, poisoning and procedural complications			6 (6.9%)	2 (4.4%)	8 (6.1%)				
		Mild	5 (5.7%)	2 (4.4%)	7 (5.3%)	1.3003 [0.2485, 6.8049]	1.2926 [0.2564, 6.5167] 0.7531	0.0130 [-0.0658, 0.0919]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 46 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Injury, poisoning and procedural complications		Moderate	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Severe	0	0	0				
	Head injury		1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5181 [0.0326, 8.2257]	0.5181 [0.0328, 8.1946] 0.6346	-0.0107 [-0.0597, 0.0382]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Skin laceration		2 (2.3%)	0	2 (1.5%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Injury, poisoning and procedural complications	Animal scratch		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye injury		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Joint injury		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 48 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Injury, poisoning and procedural complications	Ligament sprain		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
Reproductive system and breast disorders			5 (5.7%)	0	5 (3.8%)				
		Mild	5 (5.7%)	0	5 (3.8%)	3.2904 [0.3828, 28.2835]	3.1345 [0.3874, 25.3632] 0.1035	0.0575 [0.0086, 0.1064]	0.9784
		Moderate	0	0	0				
		Severe	0	0	0				
	Gynaecomastia		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7419 [0.1267, 59.3349]	2.6531 [0.1322, 53.2292] 0.3041	0.0231 [-0.0085, 0.0547]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 49 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Reproductive system and breast disorders	Balanoposthitis		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Pelvic fluid collection		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Testicular appendage torsion		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 50 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Musculoskeletal and connective tissue disorders			4 (4.6%)	0	4 (3.0%)				
		Mild	4 (4.6%)	0	4 (3.0%)	2.5921 [0.2861, 23.4855]	2.4990 [0.2924, 21.3562] 0.1454	0.0461 [0.0020, 0.0901]	0.9986
		Moderate	0	0	0				
		Severe	0	0	0				
	Arthralgia		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7419 [0.1267, 59.3349]	2.6531 [0.1322, 53.2292] 0.3041	0.0231 [-0.0085, 0.0547]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain in extremity		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Musculoskeletal and connective tissue disorders	Scoliosis		0	0	0				
		Mild	0	0	0				0.9710
		Moderate	0	0	0				
		Severe	0	0	0				
Nervous system disorders			1 (1.1%)	3 (6.7%)	4 (3.0%)				
		Mild	1 (1.1%)	3 (6.7%)	4 (3.0%)	0.1560 [0.0153, 1.5863]	0.1736 [0.0190, 1.5841] 0.0793	-0.0550 [-0.1306, 0.0207]	0.9268
		Moderate	0	0	0				
		Severe	0	0	0				
	Headache		0	3 (6.7%)	3 (2.3%)				
		Mild	0	3 (6.7%)	3 (2.3%)	0.0663 [0.0033, 1.3379]	0.0758 [0.0041, 1.4122] 0.0149	-0.0665 [-0.1393, 0.0063]	0.9971
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Nervous system disorders	Dizziness		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9770
		Moderate	0	0	0				
		Severe	0	0	0				
Cardiac disorders			2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	1.6040 [0.1622, 15.8650]	1.5834 [0.1694, 14.8003] 0.3093	0.0230 [-0.0085, 0.0545]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Myocarditis		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 53 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Cardiac disorders	Wandering pacemaker		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
Congenital, familial and genetic disorders			2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7419 [0.1267, 59.3349]	2.6531 [0.1322, 53.2292] 0.3041	0.0231 [-0.0085, 0.0547]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				
	Buried penis syndrome		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 54 of 105

Table 1.19 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=87) | Daily rhGH (N=45) | Total (N=132) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Congenital, familial and genetic disorders	Supernumerary teeth		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
Ear and labyrinth disorders			1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5000 [0.0296, 8.4388]	0.5128 [0.0338, 7.7761] 0.6275	-0.0109 [-0.0590, 0.0373]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Cerumen impaction		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 55 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Ear and labyrinth disorders	Motion sickness		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
Endocrine disorders			2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7419 [0.1267, 59.3349]	2.6531 [0.1322, 53.2292] 0.3041	0.0231 [-0.0085, 0.0547]	0.9572
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypothyroidism		2 (2.3%)	0	2 (1.5%)				
		Mild	2 (2.3%)	0	2 (1.5%)	2.7419 [0.1267, 59.3349]	2.6531 [0.1322, 53.2292] 0.3041	0.0231 [-0.0085, 0.0547]	0.9795
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 56 of 105

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Endocrine disorders	Precocious puberty		0	0	0				
		Mild	0	0	0				0.9773
		Moderate	0	0	0				
		Severe	0	0	0				
Immune system disorders			1 (1.1%)	1 (2.2%)	2 (1.5%)				
		Mild	1 (1.1%)	1 (2.2%)	2 (1.5%)	0.5181 [0.0326, 8.2257]	0.5181 [0.0328, 8.1946] 0.6346	-0.0107 [-0.0597, 0.0382]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Food allergy		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypersensitivity		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Male

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Renal and urinary disorders			0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
	Nocturia		0	1 (2.2%)	1 (0.8%)				
		Mild	0	1 (2.2%)	1 (0.8%)	0.1684 [0.0066, 4.2878]	0.1769 [0.0075, 4.1902] 0.1659	-0.0222 [-0.0652, 0.0208]	0.9754
		Moderate	0	0	0				
		Severe	0	0	0				
Vascular disorders			1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Vascular disorders	Cyanosis		1 (1.1%)	0	1 (0.8%)				
		Mild	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Any adverse event			11 (84.6%)	7 (87.5%)	18 (85.7%)			
		Mild	10 (76.9%)	7 (87.5%)	17 (81.0%)	0.4878 [0.0436, 5.4633]	0.8786 [0.5852, 1.3193] 0.5689	-0.1061 [-0.4361, 0.2240]
		Moderate	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Severe	0	0	0			
Infections and infestations			6 (46.2%)	6 (75.0%)	12 (57.1%)			
		Mild	5 (38.5%)	6 (75.0%)	11 (52.4%)	0.1744 [0.0209, 1.4545]	0.5203 [0.2451, 1.1045] 0.1087	-0.3586 [-0.7386, 0.0214]
		Moderate	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 60 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Upper respiratory tract infection		5 (38.5%)	5 (62.5%)	10 (47.6%)			
		Mild	5 (38.5%)	5 (62.5%)	10 (47.6%)	0.3285 [0.0447, 2.4127]	0.6260 [0.2793, 1.4031] 0.2892	-0.2323 [-0.6297, 0.1650]
		Moderate	0	0	0			
		Severe	0	0	0			
	Bronchitis		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0808 [-0.0671, 0.2287]
		Moderate	0	0	0			
		Severe	0	0	0			
	Chronic sinusitis		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Conjunctivitis		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastroenteritis		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
		Moderate	0	0	0			
		Severe	0	0	0			
	Influenza		1 (7.7%)	0	1 (4.8%)			
		Mild	0	0	0			
		Moderate	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Severe	0	0	0			
	Nasopharyngitis		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Pharyngitis		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			
	Respiratory tract infection		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			
	Urinary tract infection		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 63 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Abscess limb		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Bacterial infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Chronic tonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Folliculitis		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Gastrointestinal bacterial infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hand-foot-and-mouth disease		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpangina		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpes virus 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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Infectious mononucleosis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Laryngitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Mumps		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Myringitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Oral herpes		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 66 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

| System Organ Class | Preferred Term | Severity | TransCon hGH (N=13) | Daily rhGH (N=8) | Total (N=21) | Lonapegsomatropin vs. Daily rhGH [a] | | |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Otitis media		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			
	Periodontitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Peritonsillar abscess		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 67 of 105

Table 1.19 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Pulpitis dental		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			
	Sinobronchitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinusitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Subcutaneous abscess		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Tonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tonsillitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tracheitis		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations			3 (23.1%)	4 (50.0%)	7 (33.3%)			
		Mild	3 (23.1%)	4 (50.0%)	7 (33.3%)	0.2143 [0.0245, 1.8774]	0.4500 [0.1494, 1.3558] 0.1658	-0.2778 [-0.6553, 0.0998]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose increased		0	4 (50.0%)	4 (19.0%)			
		Mild	0	4 (50.0%)	4 (19.0%)	0.0265 [0.0010, 0.6694]	0.0707 [0.0045, 1.1214] 0.0039	-0.5051 [-0.8498, -0.1603]
		Moderate	0	0	0			
		Severe	0	0	0			
	Insulin-like growth factor increased		3 (23.1%)	1 (12.5%)	4 (19.0%)			
		Mild	3 (23.1%)	1 (12.5%)	4 (19.0%)	2.1429 [0.1694, 27.1035]	1.8000 [0.2378, 13.6267] 0.5637	0.1010 [-0.2120, 0.4140]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 70 of 105

Table 1.19 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Cortisol decreased		1 (7.7%)	1 (12.5%)	2 (9.5%)			
		Mild	1 (7.7%)	1 (12.5%)	2 (9.5%)	0.5556 [0.0282, 10.9333]	0.6000 [0.0454, 7.9215] 0.7055	-0.0505 [-0.3175, 0.2165]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose abnormal		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			
	Liver function test abnormal		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 71 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Alanine aminotransferase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Aspartate aminotransferase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Basophil count increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood alkaline phosphatase 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Blood cholesterol increased		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 lactate dehydrogenase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood phosphorus 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood potassium increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood pressure 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			
	Blood triglycerides 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Blood urea increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood uric acid increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram ST segment abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram T wave peaked		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 75 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Electrocardiogram high voltage		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			
	Haemoglobin decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme abnormal		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Hepatic enzyme increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Lipids increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Low density lipoprotein increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroid function test abnormal		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.

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Thyroxine free decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tri-iodothyronine free 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			
Gastrointestinal disorders			3 (23.1%)	1 (12.5%)	4 (19.0%)			
		Mild	3 (23.1%)	1 (12.5%)	4 (19.0%)	1.8750 [0.1891, 18.5933]	1.8750 [0.1849, 19.0177] 0.5689	0.1061 [-0.2466, 0.4588]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Abdominal pain		1 (7.7%)	1 (12.5%)	2 (9.5%)			
		Mild	1 (7.7%)	1 (12.5%)	2 (9.5%)	0.6250 [0.0395, 9.8915]	0.6250 [0.0363, 10.7605] 0.7439	-0.0455 [-0.3266, 0.2357]
		Moderate	0	0	0			
		Severe	0	0	0			
	Diarrhoea		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Moderate	0	0	0			
		Severe	0	0	0			
	Toothache		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal distension		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 79 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointesti nal disorders	Abdominal pain upper		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			
	Dyspepsia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Enteritis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastrointesti nal 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Nausea		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Noninfective gingivitis		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			
Nervous system disorders			1 (7.7%)	3 (37.5%)	4 (19.0%)			
		Mild	1 (7.7%)	3 (37.5%)	4 (19.0%)	0.1449 [0.0123, 1.7047]	0.2027 [0.0241, 1.7030] 0.1095	-0.2980 [-0.6662, 0.0702]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 81 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Nervous system disorders	Dizziness		1 (7.7%)	1 (12.5%)	2 (9.5%)			
		Mild	1 (7.7%)	1 (12.5%)	2 (9.5%)	0.5556 [0.0282, 10.9333]	0.6000 [0.0454, 7.9215] 0.7055	-0.0505 [-0.3175, 0.2165]
		Moderate	0	0	0			
		Severe	0	0	0			
	Headache		0	2 (25.0%)	2 (9.5%)			
		Mild	0	2 (25.0%)	2 (9.5%)	0.1596 [0.0131, 1.9385]	0.2318 [0.0291, 1.8483] 0.0753	-0.2475 [-0.5471, 0.0521]
		Moderate	0	0	0			
		Severe	0	0	0			
Respiratory, thoracic and mediastinal disorders			4 (30.8%)	0	4 (19.0%)			
		Mild	4 (30.8%)	0	4 (19.0%)	4.4943 [0.4152, 48.6502]	3.1741 [0.4327, 23.2846] 0.0980	0.3081 [0.0571, 0.5591]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Cough		4 (30.8%)	0	4 (19.0%)			
		Mild	4 (30.8%)	0	4 (19.0%)	4.4943 [0.4152, 48.6502]	3.1741 [0.4327, 23.2846] 0.0980	0.3081 [0.0571, 0.5591]
		Moderate	0	0	0			
		Severe	0	0	0			
	Adenoidal hypertrophy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Allergic cough		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Asthma		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Nasal congestion		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal obstruction		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Oropharyngeal pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Productive cough		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 84 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		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			
General disorders and administration site conditions			1 (7.7%)	2 (25.0%)	3 (14.3%)			
		Mild	1 (7.7%)	2 (25.0%)	3 (14.3%)	0.2222 [0.0153, 3.2212]	0.3000 [0.0340, 2.6450] 0.2623	-0.1768 [-0.5029, 0.1493]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site swelling		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pyrexia		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 86 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site bruising		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site erythema		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site haemorrhage		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 87 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site pruritus		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site reaction		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Peripheral 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 88 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders			3 (23.1%)	0	3 (14.3%)			
		Mild	3 (23.1%)	0	3 (14.3%)	3.4405 [0.3098, 38.2094]	2.6666 [0.3538, 20.0978] 0.1624	0.2323 [0.0029, 0.4617]
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria		2 (15.4%)	0	2 (9.5%)			
		Mild	2 (15.4%)	0	2 (9.5%)	2.4420 [0.2068, 28.8365]	2.0858 [0.2615, 16.6347] 0.2605	0.1566 [-0.0407, 0.3538]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	3.0000 [0.0780, 115.3380]	2.2500 [0.1329, 38.0878] 0.4142	0.0808 [-0.0671, 0.2287]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis contact		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Eczema		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		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			
	Dyshidrotic 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 90 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Urticaria chronic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria papular		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Endocrine disorders			0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			
	Precocious puberty		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 91 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Endocrine disorders	Hypothyroidism		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Eye disorders			0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
		Moderate	0	0	0			
		Severe	0	0	0			
	Vernal keratoconjunctivitis		0	1 (12.5%)	1 (4.8%)			
		Mild	0	1 (12.5%)	1 (4.8%)	0.1429 [0.0034, 5.9458]	0.2500 [0.0148, 4.2320] 0.2207	-0.1212 [-0.3479, 0.1055]
		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Corneal epithelium defect		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye pain		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			
	Myopia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Papilloedema		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 93 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Refraction disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vitreous opacities		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Xerophthalmia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Musculoskeletal and connective tissue disorders			1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Musculoskeletal and connective tissue disorders	Scoliosis		1 (7.7%)	0	1 (4.8%)			
		Mild	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]
		Moderate	0	0	0			
		Severe	0	0	0			
	Arthralgia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain in extremity		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Blood and lymphatic 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders	Anaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Granulocytopenia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypochromic anaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Lymphadenitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thymus 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 96 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Cardiac disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Myocarditis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Wandering pacemaker		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Congenital, familial and genetic 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Congenital, familial and genetic disorders	Buried penis syndrome		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Supernumerary teeth		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			
		Severe	0	0	0			
	Cerumen impaction		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 98 of 105

Anhang 4-H   Seite 275 von 682

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Ear and labyrinth disorders	Motion sickness		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			
	Food allergy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypersensitivity		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 99 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Animal scratch		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye injury		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			
	Joint 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 100 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications	Ligament sprain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Skin laceration		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			
		Severe	0	0	0			
	Calcium deficiency		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Decreased appetite		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypercholesterolaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperglycaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperlipidaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypertriglyceridaemia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 102 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Hyperuricaemi a		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			
	Nocturia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Reproductive system and breast disorders	Balanoposthitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gynaecomastia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pelvic fluid collection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Testicular appendage torsion		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 104 of 105

Table 1.19 Treatment Emergent Adverse Events by Maximum Severity of Event: Incidences by System Organ Class and Preferred Term,
subgroup analysis by gender
Safety Population

Female

System Organ Class	Preferred Term	Severity	TransCon hGH (N=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Vascular disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cyanosis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 105 of 105

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Any adverse event			25 (100.0%)	13 (100.0%)	38 (100.0%)				
		Mild	25 (100.0%)	11 (84.6%)	36 (94.7%)	6.6868 [0.6183, 72.3156]	1.1526 [0.9307, 1.4275] 0.0486	0.1544 [-0.0419, 0.3508]	0.9729
		Moderate	0	2 (15.4%)	2 (5.3%)	0.1495 [0.0138, 1.6173]	0.1852 [0.0213, 1.6070] 0.0486	-0.1544 [-0.3508, 0.0419]	0.9646
		Severe	0	0	0				0.9739
Infections and infestations			11 (44.0%)	9 (69.2%)	20 (52.6%)				
		Mild	11 (44.0%)	7 (53.8%)	18 (47.4%)	0.6230 [0.1476, 2.6289]	0.8083 [0.4314, 1.5147] 0.5243	-0.1034 [-0.4160, 0.2091]	0.7158
		Moderate	0	2 (15.4%)	2 (5.3%)	0.1495 [0.0138, 1.6173]	0.1852 [0.0213, 1.6070] 0.0486	-0.1544 [-0.3508, 0.0419]	0.9741
		Severe	0	0	0				0.9739

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 1 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Upper respiratory tract infection		9 (36.0%)	8 (61.5%)	17 (44.7%)				
		Mild	9 (36.0%)	6 (46.2%)	15 (39.5%)	0.5636 [0.1193, 2.6637]	0.7670 [0.3829, 1.5362] 0.4699	-0.1079 [-0.4004, 0.1845]	0.8142
		Moderate	0	2 (15.4%)	2 (5.3%)	0.1495 [0.0138, 1.6173]	0.1852 [0.0213, 1.6070] 0.0486	-0.1544 [-0.3508, 0.0419]	0.9960
		Severe	0	0	0				
	Otitis media		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5098 [0.0306, 8.5057]	0.5098 [0.0306, 8.4827] 0.6323	-0.0375 [-0.2047, 0.1297]	0.9783
		Moderate	0	0	0				
		Severe	0	0	0				
	Pharyngitis		0	2 (15.4%)	2 (5.3%)				
		Mild	0	2 (15.4%)	2 (5.3%)	0.1495 [0.0138, 1.6173]	0.1852 [0.0213, 1.6070] 0.0486	-0.1544 [-0.3508, 0.0419]	0.9509
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 2 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Pneumonia		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.4286 [0.0196, 9.3641]	0.5000 [0.0411, 6.0820] 0.6000	-0.0390 [-0.1938, 0.1158]	0.9794
		Moderate	0	0	0				
		Severe	0	0	0				
	Tonsillitis		2 (8.0%)	0	2 (5.3%)				
		Mild	2 (8.0%)	0	2 (5.3%)	1.7621 [0.1647, 18.8493]	1.6667 [0.1921, 14.4633] 0.3103	0.0795 [-0.0266, 0.1855]	0.9768
		Moderate	0	0	0				
		Severe	0	0	0				
	Abscess limb		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				
	Bronchitis		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9810
		Moderate	0	0	0				0.9815
		Severe	0	0	0				0.9815

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 3 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Hordeolum		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				
	Laryngitis		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9555
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasopharyngitis		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9782
		Moderate	0	0	0				0.9751
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 4 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Otitis media acute		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9555
		Moderate	0	0	0				
		Severe	0	0	0				
	Respiratory tract infection		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9715
		Moderate	0	0	0				
		Severe	0	0	0				
	Rhinitis		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9570
		Moderate	0	0	0				
		Severe	0	0	0				
	Sinusitis		0	1 (7.7%)	1 (2.6%)				
		Mild	0	0	0				0.9815

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 5 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Sinusitis	Moderate	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9752
		Severe	0	0	0				
	Urinary tract infection		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9752
		Moderate	0	0	0				
		Severe	0	0	0				
	Bacterial infection		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Chronic sinusitis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Chronic tonsillitis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Conjunctivitis		0	0	0				
		Mild	0	0	0				0.9989
		Moderate	0	0	0				
		Severe	0	0	0				
	Folliculitis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastroenteritis		0	0	0				
		Mild	0	0	0				0.9970
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 7 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Infections and infestations	Gastroenteritis viral		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal bacterial infection		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Hand-foot-and-mouth disease		0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				
	Herpangina		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Herpes virus infection		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Infectious mononucleosis		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Influenza		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9815
		Severe	0	0	0				
	Mumps		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Myringitis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Oral herpes		0	0	0				
		Mild	0	0	0				0.9989
		Moderate	0	0	0				
		Severe	0	0	0				
	Periodontitis		0	0	0				
		Mild	0	0	0				0.9786
		Moderate	0	0	0				
		Severe	0	0	0				
	Peritonsillar abscess		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9751
		Severe	0	0	0				
	Pulpitis dental		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Sinobronchitis		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 10 of 107

Table 1.20 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=25) | Daily rhGH (N=13) | Total (N=38) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI][b]	RR [95 %-CI][b] p-value[c]	RD [95 %-CI][b]	
Infections and infestations	Subcutaneous abscess		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9815
		Severe	0	0	0				
	Tonsillitis bacterial		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	0	0	0				0.9815
	Tracheitis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Varicella		0	0	0				
		Mild	0	0	0				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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations			12 (48.0%)	8 (61.5%)	20 (52.6%)				
		Mild	12 (48.0%)	8 (61.5%)	20 (52.6%)	0.5893 [0.1560, 2.2257]	0.7756 [0.4194, 1.4344] 0.4230	-0.1379 [-0.4766, 0.2007]	0.5510
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose increased		4 (16.0%)	6 (46.2%)	10 (26.3%)				
		Mild	4 (16.0%)	6 (46.2%)	10 (26.3%)	0.2172 [0.0464, 1.0167]	0.3485 [0.1201, 1.0113] 0.0497	-0.2999 [-0.6044, 0.0047]	0.3833
		Moderate	0	0	0				
		Severe	0	0	0				
	Insulin-like growth factor increased		7 (28.0%)	1 (7.7%)	8 (21.1%)				
		Mild	7 (28.0%)	1 (7.7%)	8 (21.1%)	4.1905 [0.5089, 34.5076]	3.6275 [0.4720, 27.8770] 0.1527	0.2009 [-0.0340, 0.4358]	0.7014
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 12 of 107

Table 1.20 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. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Alanine aminotransferase increased		2 (8.0%)	0	2 (5.3%)				
		Mild	2 (8.0%)	0	2 (5.3%)	3.0645 [0.1324, 70.9387]	2.7778 [0.1474, 52.3507] 0.2936	0.0810 [-0.0259, 0.1878]	0.9758
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood iron increased		2 (8.0%)	0	2 (5.3%)				
		Mild	2 (8.0%)	0	2 (5.3%)	1.7621 [0.1647, 18.8493]	1.6667 [0.1921, 14.4633] 0.3103	0.0795 [-0.0266, 0.1855]	0.9583
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood phosphorus increased		2 (8.0%)	0	2 (5.3%)				
		Mild	2 (8.0%)	0	2 (5.3%)	3.0645 [0.1324, 70.9387]	2.7778 [0.1474, 52.3507] 0.2936	0.0810 [-0.0259, 0.1878]	0.9749
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Low density lipoprotein increased		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5098 [0.0306, 8.5057]	0.5098 [0.0306, 8.4827] 0.6323	-0.0375 [-0.2047, 0.1297]	0.9870
		Moderate	0	0	0				
		Severe	0	0	0				
	Aspartate aminotransferase increased		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9978
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood alkaline phosphatase increased		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9694
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 14 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood cholesterol increased		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose abnormal		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9716
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood triglycerides increased		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9692
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 15 of 107

Table 1.20 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. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood uric acid increased		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9749
		Moderate	0	0	0				
		Severe	0	0	0				
	Cortisol decreased		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9785
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram ST segment abnormal		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1373 [0.0044, 4.2556]	0.1852 [0.0091, 3.7499] 0.1573	-0.0780 [-0.2236, 0.0677]	0.9752
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 16 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Eosinophil count increased		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9785
		Moderate	0	0	0				
		Severe	0	0	0				
	Thyroid function test abnormal		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9752
		Moderate	0	0	0				
		Severe	0	0	0				
	Thyroxine free decreased		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 17 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Basophil count increased		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood lactate dehydrogenase increased		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood potassium increased		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood pressure increased		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				

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

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood thyroid stimulating hormone increased		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood urea increased		0	0	0				
		Mild	0	0	0				0.9791
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram T wave peaked		0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram high voltage		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 19 of 107

Table 1.20 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. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Haemoglobin decreased		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Hepatic enzyme abnormal		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Hepatic enzyme increased		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Lipids increased		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 20 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Liver function test abnormal		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Tri-iodothyronine free increased		0	0	0				
		Mild	0	0	0				0.9989
		Moderate	0	0	0				
		Severe	0	0	0				
	White blood cell count decreased		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
Gastrointestinal disorders			8 (32.0%)	3 (23.1%)	11 (28.9%)				
		Mild	8 (32.0%)	3 (23.1%)	11 (28.9%)	1.5714 [0.3380, 7.3051]	1.3896 [0.4421, 4.3674] 0.5716	0.0900 [-0.2037, 0.3836]	0.2004
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 21 of 107

Table 1.20 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. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Diarrhoea		3 (12.0%)	1 (7.7%)	4 (10.5%)				
		Mild	3 (12.0%)	1 (7.7%)	4 (10.5%)	1.6444 [0.1530, 17.6779]	1.5686 [0.1786, 13.7793] 0.6862	0.0435 [-0.1493, 0.2363]	0.3078
		Moderate	0	0	0				
		Severe	0	0	0				
	Toothache		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5000 [0.0275, 9.0764]	0.5294 [0.0373, 7.5041] 0.6407	-0.0360 [-0.1979, 0.1259]	0.9987
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal distension		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal pain		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9555
		Moderate	0	0	0				
		Severe	0	0	0				

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

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Abdominal pain upper		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9978
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyspepsia		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1373 [0.0044, 4.2556]	0.1852 [0.0091, 3.7499] 0.1573	-0.0780 [-0.2236, 0.0677]	0.9680
		Moderate	0	0	0				
		Severe	0	0	0				
	Enteritis		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9555
		Moderate	0	0	0				
		Severe	0	0	0				
	Constipation		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 23 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Gastrointestinal disorder		0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				
	Nausea		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Noninfective gingivitis		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Vomiting		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 24 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders			6 (24.0%)	3 (23.1%)	9 (23.7%)				
		Mild	6 (24.0%)	3 (23.1%)	9 (23.7%)	1.0596 [0.2188, 5.1320]	1.0455 [0.3108, 3.5163] 0.9436	0.0105 [-0.2742, 0.2952]	0.4145
		Moderate	0	0	0				0.9791
		Severe	0	0	0				
	Cough		5 (20.0%)	1 (7.7%)	6 (15.8%)				
		Mild	5 (20.0%)	1 (7.7%)	6 (15.8%)	3.1282 [0.3133, 31.2386]	2.6275 [0.3465, 19.9223] 0.3258	0.1244 [-0.0861, 0.3350]	0.9800
		Moderate	0	0	0				0.9791
		Severe	0	0	0				
	Rhinitis allergic		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.4286 [0.0196, 9.3641]	0.5000 [0.0411, 6.0820] 0.6000	-0.0390 [-0.1938, 0.1158]	0.6916
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 25 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Allergic cough		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal congestion		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9752
		Moderate	0	0	0				
		Severe	0	0	0				
	Oropharyngeal pain		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				

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

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9688
		Moderate	0	0	0				
		Severe	0	0	0				
	Adenoidal hypertrophy		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Asthma		0	0	0				
		Mild	0	0	0				0.9999
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal obstruction		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Productive cough		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Sleep apnoea syndrome		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
General disorders and administration site conditions			4 (16.0%)	2 (15.4%)	6 (15.8%)				
		Mild	4 (16.0%)	2 (15.4%)	6 (15.8%)	1.0769 [0.1563, 7.4204]	1.0588 [0.2380, 4.7110] 0.9412	0.0090 [-0.2236, 0.2416]	0.6902
		Moderate	0	0	0				0.9999
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 28 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Pyrexia		4 (16.0%)	0	4 (10.5%)				
		Mild	4 (16.0%)	0	4 (10.5%)	6.3333 [0.3038, 132.0494]	5.0000 [0.2987, 83.6853] 0.1208	0.1619 [0.0177, 0.3062]	0.9675
		Moderate	0	0	0				0.9989
		Severe	0	0	0				
	Injection site swelling		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9752
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9752
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 29 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site bruising		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site erythema		0	0	0				
		Mild	0	0	0				0.9989
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site haemorrhage		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site pain		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 30 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site pruritus		0	0	0				
		Mild	0	0	0				0.9999
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site reaction		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				0.9815
		Severe	0	0	0				
	Peripheral swelling		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 31 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders			3 (12.0%)	3 (23.1%)	6 (15.8%)				
		Mild	3 (12.0%)	3 (23.1%)	6 (15.8%)	0.4539 [0.0776, 2.6558]	0.5195 [0.1215, 2.2208] 0.3866	-0.1109 [-0.3730, 0.1511]	0.4922
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypertriglyceridaemia		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5000 [0.0275, 9.0764]	0.5294 [0.0373, 7.5041] 0.6407	-0.0360 [-0.1979, 0.1259]	0.2944
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperuricaemia		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5192 [0.0338, 7.9646]	0.5192 [0.0338, 7.9815] 0.6323	-0.0375 [-0.2067, 0.1317]	0.9783
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Metabolism and nutrition disorders	Decreased appetite		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9692
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypercholesterolaemia		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1373 [0.0044, 4.2556]	0.1852 [0.0091, 3.7499] 0.1573	-0.0780 [-0.2236, 0.0677]	0.9757
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperglycaemia		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9752
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 33 of 107

Table 1.20 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. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders	Calcium deficiency		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperlipidaemia		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
Nervous system disorders			1 (4.0%)	3 (23.1%)	4 (10.5%)				
		Mild	1 (4.0%)	3 (23.1%)	4 (10.5%)	0.1250 [0.0108, 1.4485]	0.1765 [0.0213, 1.4615] 0.0703	-0.1889 [-0.4264, 0.0486]	0.9139
		Moderate	0	0	0				
		Severe	0	0	0				
	Dizziness		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5000 [0.0275, 9.0764]	0.5294 [0.0373, 7.5041] 0.6407	-0.0360 [-0.1979, 0.1259]	0.9783
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 34 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Nervous system disorders	Headache		0	2 (15.4%)	2 (5.3%)				
		Mild	0	2 (15.4%)	2 (5.3%)	0.0857 [0.0037, 2.0094]	0.1111 [0.0059, 2.0940] 0.0473	-0.1529 [-0.3487, 0.0428]	0.9980
		Moderate	0	0	0				
		Severe	0	0	0				
Eye disorders			2 (8.0%)	1 (7.7%)	3 (7.9%)				
		Mild	2 (8.0%)	1 (7.7%)	3 (7.9%)	1.0417 [0.0872, 12.4412]	1.0392 [0.0995, 10.8512] 0.9748	0.0030 [-0.1782, 0.1842]	0.8935
		Moderate	0	0	0				0.9815
		Severe	0	0	0				
	Papilloedema		1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5000 [0.0275, 9.0764]	0.5294 [0.0373, 7.5041] 0.6407	-0.0360 [-0.1979, 0.1259]	0.9987
		Moderate	0	0	0				
		Severe	0	0	0				
	Myopia		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders	Conjunctivitis allergic		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Corneal epithelium defect		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye pain		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye swelling		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9815
		Severe	0	0	0				
	Refraction disorder		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 36 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders	Vernal keratoconjunctivitis		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Vitreous opacities		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Xerophthalmia		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
Skin and subcutaneous tissue disorders			2 (8.0%)	1 (7.7%)	3 (7.9%)				
		Mild	2 (8.0%)	1 (7.7%)	3 (7.9%)	1.0417 [0.0872, 12.4412]	1.0392 [0.0995, 10.8512] 0.9748	0.0030 [-0.1782, 0.1842]	0.3707
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 37 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Dermatitis contact		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				
	Rash		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9752
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 38 of 107

Table 1.20 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. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Urticaria papular		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.8000 [0.0596, 54.3309]	1.6667 [0.0823, 33.7487] 0.4795	0.0390 [-0.0369, 0.1149]	0.9978
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis allergic		0	0	0				
		Mild	0	0	0				0.9999
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyshidrotic eczema		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 39 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Eczema		0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria chronic		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
Blood and lymphatic system disorders			1 (4.0%)	1 (7.7%)	2 (5.3%)				
		Mild	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5000 [0.0275, 9.0764]	0.5294 [0.0373, 7.5041] 0.6407	-0.0360 [-0.1979, 0.1259]	0.4231
		Moderate	0	0	0				0.9815
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 40 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Blood and lymphatic system disorders	Anaemia		0	1 (7.7%)	1 (2.6%)				
		Mild	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypochromic anaemia		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				
	Granulocytopenia		0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				
	Lymphadenitis		0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 41 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Blood and lymphatic system disorders	Thymus disorder		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9815
		Severe	0	0	0				
Musculoskeletal and connective tissue disorders			2 (8.0%)	0	2 (5.3%)				
		Mild	2 (8.0%)	0	2 (5.3%)	3.0645 [0.1324, 70.9387]	2.7778 [0.1474, 52.3507] 0.2936	0.0810 [-0.0259, 0.1878]	0.9987
		Moderate	0	0	0				
		Severe	0	0	0				
	Arthralgia		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9978
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 42 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Musculoskeletal and connective tissue disorders	Scoliosis		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain in extremity		0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				
Endocrine disorders			1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9692
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 43 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Endocrine disorders	Hypothyroidism		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9978
		Moderate	0	0	0				
		Severe	0	0	0				
	Precocious puberty		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
Immune system disorders			1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9555
		Moderate	0	0	0				
		Severe	0	0	0				
	Food allergy		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 44 of 107

Table 1.20 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=25) | Daily rhGH (N=13) | Total (N=38) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Immune system disorders	Hypersensitivity		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
Injury, poisoning and procedural complications			1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9731
		Moderate	0	0	0				0.9815
		Severe	0	0	0				
	Head injury		1 (4.0%)	0	1 (2.6%)				
		Mild	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9555
		Moderate	0	0	0				
		Severe	0	0	0				
	Animal scratch		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 45 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Injury, poisoning and procedural complications	Eye injury		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Joint injury		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Ligament sprain		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Skin laceration		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				0.9815
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 46 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Cardiac disorders			0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				
	Myocarditis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Wandering pacemaker		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
Congenital, familial and genetic disorders			0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 47 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Congenital, familial and genetic disorders	Buried penis syndrome		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Supernumerary teeth		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
Ear and labyrinth disorders			0	0	0				
		Mild	0	0	0				0.9989
		Moderate	0	0	0				
		Severe	0	0	0				
	Cerumen impaction		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 48 of 107

Table 1.20 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Ear and labyrinth disorders	Motion sickness		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
Renal and urinary disorders			0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
	Nocturia		0	0	0				
		Mild	0	0	0				0.9751
		Moderate	0	0	0				
		Severe	0	0	0				
Reproductive system and breast disorders			0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 49 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Reproductive system and breast disorders	Balanoposthitis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Gynaecomastia		0	0	0				
		Mild	0	0	0				0.9739
		Moderate	0	0	0				
		Severe	0	0	0				
	Pelvic fluid collection		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Testicular appendage torsion		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 50 of 107

Table 1.20 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=25)	Daily rhGH (N=13)	Total (N=38)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Vascular disorders			0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Cyanosis		0	0	0				
		Mild	0	0	0				0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 51 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Any adverse event			73 (97.3%)	37 (92.5%)	110 (95.7%)			
		Mild	64 (85.3%)	35 (87.5%)	99 (86.1%)	0.8310 [0.2672, 2.5844]	0.9752 [0.8393, 1.1331] 0.7509	-0.0217 [-0.1517, 0.1084]
		Moderate	7 (9.3%)	2 (5.0%)	9 (7.8%)	1.9554 [0.3868, 9.8844]	1.8666 [0.4067, 8.5672] 0.4139	0.0433 [-0.0510, 0.1377]
		Severe	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]
Infections and infestations			49 (65.3%)	26 (65.0%)	75 (65.2%)			
		Mild	45 (60.0%)	25 (62.5%)	70 (60.9%)	0.8914 [0.3955, 2.0092]	0.9588 [0.7145, 1.2867] 0.7839	-0.0257 [-0.2069, 0.1555]
		Moderate	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0654 [0.0935, 12.1464]	1.0635 [0.1001, 11.2936] 0.9596	0.0016 [-0.0590, 0.0621]
		Severe	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]

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

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Upper respiratory tract infection		35 (46.7%)	22 (55.0%)	57 (49.6%)			
		Mild	35 (46.7%)	21 (52.5%)	56 (48.7%)	0.7842 [0.3595, 1.7108]	0.8877 [0.6099, 1.2922] 0.5420	-0.0590 [-0.2479, 0.1299]
		Moderate	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Severe	0	0	0			
	Bronchitis		8 (10.7%)	2 (5.0%)	10 (8.7%)			
		Mild	6 (8.0%)	2 (5.0%)	8 (7.0%)	1.7143 [0.3088, 9.5175]	1.5882 [0.3562, 7.0814] 0.5383	0.0295 [-0.0578, 0.1167]
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Severe	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
	Tonsillitis		4 (5.3%)	4 (10.0%)	8 (7.0%)			
		Mild	4 (5.3%)	4 (10.0%)	8 (7.0%)	0.5064 [0.1196, 2.1446]	0.5330 [0.1408, 2.0177] 0.3524	-0.0467 [-0.1526, 0.0592]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
| | | | TransCon hGH (N=75) | Daily rhGH (N=40) | Total (N=115) | OR [95 %-CI] [b] | RR [95 %-CI] [b] p-value[c] | RD [95 %-CI] [b] |
System Organ Class	Preferred Term	Severity						
Infections and infestations	Respiratory tract infection		5 (6.7%)	2 (5.0%)	7 (6.1%)			
		Mild	5 (6.7%)	2 (5.0%)	7 (6.1%)	1.3587 [0.2527, 7.3057]	1.3360 [0.2710, 6.5852] 0.7210	0.0168 [-0.0714, 0.1050]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasopharyngitis		2 (2.7%)	3 (7.5%)	5 (4.3%)			
		Mild	2 (2.7%)	2 (5.0%)	4 (3.5%)	0.5201 [0.0704, 3.8397]	0.5330 [0.0780, 3.6415] 0.5186	-0.0234 [-0.1001, 0.0534]
		Moderate	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Severe	0	0	0			
	Gastroenteritis		1 (1.3%)	2 (5.0%)	3 (2.6%)			
		Mild	1 (1.3%)	2 (5.0%)	3 (2.6%)	0.2543 [0.0220, 2.9416]	0.2653 [0.0248, 2.8401] 0.2420	-0.0367 [-0.1090, 0.0355]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 54 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Herpangina		3 (4.0%)	0	3 (2.6%)			
		Mild	3 (4.0%)	0	3 (2.6%)	4.1111 [0.2010, 84.0981]	3.8000 [0.2070, 69.7611] 0.1985	0.0398 [-0.0044, 0.0841]
		Moderate	0	0	0			
		Severe	0	0	0			
	Periodontitis		3 (4.0%)	0	3 (2.6%)			
		Mild	3 (4.0%)	0	3 (2.6%)	2.2041 [0.2356, 20.6176]	2.1401 [0.2442, 18.7513] 0.2031	0.0400 [-0.0043, 0.0844]
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5152 [0.0303, 8.7548]	0.5294 [0.0351, 7.9749] 0.6442	-0.0118 [-0.0662, 0.0426]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Hand-foot-and-mouth disease		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	2.8462 [0.1296, 62.5223]	2.7143 [0.1372, 53.6823] 0.2987	0.0265 [-0.0098, 0.0629]
		Moderate	0	0	0			
		Severe	0	0	0			
	Oral herpes		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5319 [0.0331, 8.5570]	0.5319 [0.0330, 8.5835] 0.6510	-0.0117 [-0.0670, 0.0436]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pneumonia		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5319 [0.0331, 8.5570]	0.5319 [0.0330, 8.5835] 0.6510	-0.0117 [-0.0670, 0.0436]
		Moderate	0	0	0			
		Severe	0	0	0			
	Rhinitis		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	2.8481 [0.1309, 61.9810]	2.7381 [0.1372, 54.6396] 0.2963	0.0268 [-0.0098, 0.0633]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 56 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Varicella		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5341 [0.0336, 8.4858]	0.5341 [0.0337, 8.4595] 0.6510	-0.0117 [-0.0671, 0.0438]
		Moderate	0	0	0			
		Severe	0	0	0			
	Bacterial infection		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Chronic sinusitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 57 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Chronic tonsillitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Folliculitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastroenteritis viral		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			

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

v9.4 26MAY2023:14:13 Page 58 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Gastrointestinal bacterial infection		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpes virus infection		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Infectious mononucleosis		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Influenza		1 (1.3%)	0	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 59 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Influenza	Moderate	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Severe	0	0	0			
	Laryngitis		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Mumps		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Myringitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 60 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Otitis media		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis media acute		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Peritonsillar abscess		0	1 (2.5%)	1 (0.9%)			
		Mild	0	0	0			
		Moderate	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Severe	0	0	0			
	Pharyngitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Pulpitis dental		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinobronchitis		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinusitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Subcutaneous abscess		1 (1.3%)	0	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 62 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
						Lonapegsomatropin vs. Daily rhGH [a]		
Infections and infestations	Subcutaneous abscess	Moderate	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Severe	0	0	0			
	Tonsillitis bacterial		1 (1.3%)	0	1 (0.9%)			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
	Tracheitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abscess limb		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 63 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Hordeolum		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			
Investigations			38 (50.7%)	21 (52.5%)	59 (51.3%)			
		Mild	38 (50.7%)	21 (52.5%)	59 (51.3%)	0.9306 [0.4334, 1.9984]	0.9654 [0.6655, 1.4005] 0.8540	-0.0181 [-0.2108, 0.1746]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose increased		13 (17.3%)	12 (30.0%)	25 (21.7%)			
		Mild	13 (17.3%)	12 (30.0%)	25 (21.7%)	0.4711 [0.1856, 1.1956]	0.5794 [0.2981, 1.1264] 0.1124	-0.1260 [-0.2877, 0.0356]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Insulin-like growth factor increased		22 (29.3%)	2 (5.0%)	24 (20.9%)			
		Mild	22 (29.3%)	2 (5.0%)	24 (20.9%)	7.9515 [1.7635, 35.8532]	5.8582 [1.4524, 23.6284] 0.0022	0.2430 [0.1200, 0.3659]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood alkaline phosphatase increased		2 (2.7%)	4 (10.0%)	6 (5.2%)			
		Mild	2 (2.7%)	4 (10.0%)	6 (5.2%)	0.2311 [0.0384, 1.3887]	0.2650 [0.0522, 1.3462] 0.0884	-0.0736 [-0.1722, 0.0250]
		Moderate	0	0	0			
		Severe	0	0	0			
	Low density lipoprotein increased		3 (4.0%)	3 (7.5%)	6 (5.2%)			
		Mild	3 (4.0%)	3 (7.5%)	6 (5.2%)	0.5152 [0.0994, 2.6705]	0.5326 [0.1119, 2.5352] 0.4250	-0.0350 [-0.1281, 0.0581]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood uric acid increased		2 (2.7%)	2 (5.0%)	4 (3.5%)			
		Mild	2 (2.7%)	2 (5.0%)	4 (3.5%)	0.5201 [0.0704, 3.8397]	0.5330 [0.0780, 3.6415] 0.5186	-0.0234 [-0.1001, 0.0534]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood phosphorus increased		2 (2.7%)	1 (2.5%)	3 (2.6%)			
		Mild	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0654 [0.0935, 12.1464]	1.0635 [0.1001, 11.2936] 0.9596	0.0016 [-0.0590, 0.0621]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cortisol decreased		2 (2.7%)	1 (2.5%)	3 (2.6%)			
		Mild	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0702 [0.0941, 12.1692]	1.0685 [0.0993, 11.4975] 0.9567	0.0017 [-0.0589, 0.0623]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Eosinophil count increased		2 (2.7%)	1 (2.5%)	3 (2.6%)			
		Mild	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0702 [0.0941, 12.1692]	1.0685 [0.0993, 11.4975] 0.9567	0.0017 [-0.0589, 0.0623]
		Moderate	0	0	0			
		Severe	0	0	0			
	Alanine aminotransferase increased		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5341 [0.0336, 8.4858]	0.5341 [0.0337, 8.4595] 0.6510	-0.0117 [-0.0671, 0.0438]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose abnormal		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5319 [0.0331, 8.5570]	0.5319 [0.0330, 8.5835] 0.6510	-0.0117 [-0.0670, 0.0436]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 67 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood iron increased		0	2 (5.0%)	2 (1.7%)			
		Mild	0	2 (5.0%)	2 (1.7%)	0.0957 [0.0043, 2.1075]	0.1086 [0.0055, 2.1473] 0.0496	-0.0501 [-0.1177, 0.0175]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood triglycerides increased		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5152 [0.0303, 8.7548]	0.5294 [0.0351, 7.9749] 0.6442	-0.0118 [-0.0662, 0.0426]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood urea increased		0	2 (5.0%)	2 (1.7%)			
		Mild	0	2 (5.0%)	2 (1.7%)	0.0988 [0.0045, 2.1542]	0.1095 [0.0055, 2.1856] 0.0516	-0.0499 [-0.1174, 0.0176]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Electrocardiogram T wave peaked		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]
		Moderate	0	0	0			
		Severe	0	0	0			
	Tri-iodothyronine free increased		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5152 [0.0303, 8.7548]	0.5294 [0.0351, 7.9749] 0.6442	-0.0118 [-0.0662, 0.0426]
		Moderate	0	0	0			
		Severe	0	0	0			
	Aspartate aminotransferase increased		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 69 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Basophil count increased		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood lactate dehydrogenase increased		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood potassium increased		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood pressure increased		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		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%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram high voltage		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Haemoglobin decreased		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme abnormal		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme increased		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Lipids increased		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Liver function test abnormal		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	White blood cell count decreased		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 73 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Blood cholesterol increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram ST segment abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroid function test abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroxine free 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders			27 (36.0%)	10 (25.0%)	37 (32.2%)			
		Mild	27 (36.0%)	8 (20.0%)	35 (30.4%)	2.2093 [0.9025, 5.4079]	1.7978 [0.8967, 3.6048] 0.0755	0.1595 [-0.0070, 0.3260]
		Moderate	0	2 (5.0%)	2 (1.7%)	0.1709 [0.0172, 1.6979]	0.1817 [0.0195, 1.6926] 0.0527	-0.0500 [-0.1176, 0.0175]
		Severe	0	0	0			
	Cough		22 (29.3%)	7 (17.5%)	29 (25.2%)			
		Mild	22 (29.3%)	5 (12.5%)	27 (23.5%)	2.8712 [1.0031, 8.2179]	2.3434 [0.9569, 5.7393] 0.0423	0.1679 [0.0219, 0.3139]
		Moderate	0	2 (5.0%)	2 (1.7%)	0.1709 [0.0172, 1.6979]	0.1817 [0.0195, 1.6926] 0.0527	-0.0500 [-0.1176, 0.0175]
		Severe	0	0	0			
	Rhinorrhoea		3 (4.0%)	4 (10.0%)	7 (6.1%)			
		Mild	3 (4.0%)	4 (10.0%)	7 (6.1%)	0.3848 [0.0829, 1.7868]	0.3985 [0.0913, 1.7388] 0.2023	-0.0601 [-0.1643, 0.0441]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Asthma		2 (2.7%)	1 (2.5%)	3 (2.6%)			
		Mild	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0654 [0.0935, 12.1464]	1.0635 [0.1001, 11.2936] 0.9596	0.0016 [-0.0590, 0.0621]
		Moderate	0	0	0			
		Severe	0	0	0			
	Rhinitis allergic		2 (2.7%)	1 (2.5%)	3 (2.6%)			
		Mild	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0702 [0.0941, 12.1692]	1.0685 [0.0993, 11.4975] 0.9567	0.0017 [-0.0589, 0.0623]
		Moderate	0	0	0			
		Severe	0	0	0			
	Adenoidal hypertrophy		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 76 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Productive cough		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Sleep apnoea syndrome		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Allergic cough		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			
	Oropharyngeal pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
General disorders and administration site conditions			16 (21.3%)	11 (27.5%)	27 (23.5%)			
		Mild	14 (18.7%)	10 (25.0%)	24 (20.9%)	0.6933 [0.2783, 1.7274]	0.7464 [0.3622, 1.5383] 0.4299	-0.0634 [-0.2254, 0.0987]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions		Moderate	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0654 [0.0935, 12.1464]	1.0635 [0.1001, 11.2936] 0.9596	0.0016 [-0.0590, 0.0621]
		Severe	0	0	0			
	Pyrexia		12 (16.0%)	8 (20.0%)	20 (17.4%)			
		Mild	11 (14.7%)	7 (17.5%)	18 (15.7%)	0.8122 [0.2898, 2.2768]	0.8381 [0.3502, 2.0053] 0.6932	-0.0283 [-0.1715, 0.1148]
		Moderate	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5152 [0.0303, 8.7548]	0.5294 [0.0351, 7.9749] 0.6442	-0.0118 [-0.0662, 0.0426]
		Severe	0	0	0			
	Injection site pain		3 (4.0%)	0	3 (2.6%)			
		Mild	3 (4.0%)	0	3 (2.6%)	2.2041 [0.2356, 20.6176]	2.1401 [0.2442, 18.7513] 0.2031	0.0400 [-0.0043, 0.0844]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site pruritus		2 (2.7%)	1 (2.5%)	3 (2.6%)			
		Mild	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0702 [0.0941, 12.1692]	1.0685 [0.0993, 11.4975] 0.9567	0.0017 [-0.0589, 0.0623]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site erythema		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5341 [0.0336, 8.4858]	0.5341 [0.0337, 8.4595] 0.6510	-0.0117 [-0.0671, 0.0438]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site reaction		2 (2.7%)	0	2 (1.7%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Severe	0	0	0			

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

v9.4 26MAY2023:14:13 Page 80 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site bruising		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site haemorrhage		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Peripheral swelling		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
			TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
System Organ Class	Preferred Term	Severity						
General disorders and administration site conditions	Injection site swelling		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Gastrointestinal disorders			9 (12.0%)	9 (22.5%)	18 (15.7%)			
		Mild	9 (12.0%)	9 (22.5%)	18 (15.7%)	0.4736 [0.1721, 1.3033]	0.5336 [0.2294, 1.2413] 0.1435	-0.1050 [-0.2545, 0.0446]
		Moderate	0	0	0			
		Severe	0	0	0			
	Diarrhoea		3 (4.0%)	4 (10.0%)	7 (6.1%)			
		Mild	3 (4.0%)	4 (10.0%)	7 (6.1%)	0.3730 [0.0788, 1.7652]	0.3992 [0.0940, 1.6942] 0.2023	-0.0601 [-0.1630, 0.0428]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 82 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Dyspepsia		2 (2.7%)	1 (2.5%)	3 (2.6%)			
		Mild	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0769 [0.0922, 12.5847]	1.0732 [0.1030, 11.1844] 0.9533	0.0018 [-0.0581, 0.0617]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastrointestinal disorder		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal pain		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal pain upper		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 83 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Constipation		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Enteritis		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nausea		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Noninfective gingivitis		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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

			TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Vomiting		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal distension		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			
Metabolism and nutrition disorders			9 (12.0%)	5 (12.5%)	14 (12.2%)			
		Mild	9 (12.0%)	5 (12.5%)	14 (12.2%)	0.9571 [0.3067, 2.9863]	0.9602 [0.3348, 2.7539] 0.9388	-0.0050 [-0.1343, 0.1244]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 85 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Hypertriglyce ridaemia		6 (8.0%)	1 (2.5%)	7 (6.1%)			
		Mild	6 (8.0%)	1 (2.5%)	7 (6.1%)	3.3796 [0.3926, 29.0927]	3.2054 [0.3974, 25.8577] 0.2440	0.0550 [-0.0233, 0.1333]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypercholeste rolaemia		3 (4.0%)	2 (5.0%)	5 (4.3%)			
		Mild	3 (4.0%)	2 (5.0%)	5 (4.3%)	0.7952 [0.1293, 4.8892]	0.8002 [0.1366, 4.6870] 0.8045	-0.0100 [-0.0914, 0.0715]
		Moderate	0	0	0			
		Severe	0	0	0			
	Decreased appetite		1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5319 [0.0331, 8.5570]	0.5319 [0.0330, 8.5835] 0.6510	-0.0117 [-0.0670, 0.0436]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 86 of 107

Table 1.20 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. Daily rhGH [a] | | |
| | | | TransCon hGH (N=75) | Daily rhGH (N=40) | Total (N=115) | OR [95 %-CI] [b] | RR [95 %-CI] [b] p-value [c] | RD [95 %-CI] [b] |
System Organ Class	Preferred Term	Severity						
Metabolism and nutrition disorders	Calcium deficiency		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperlipidaemia		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperuricaemia		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperglycaemia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Eye disorders			8 (10.7%)	3 (7.5%)	11 (9.6%)			
		Mild	7 (9.3%)	3 (7.5%)	10 (8.7%)	1.2646 [0.3147, 5.0825]	1.2466 [0.3363, 4.6202] 0.7383	0.0185 [-0.0878, 0.1248]
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Severe	0	0	0			
	Refraction disorder		3 (4.0%)	2 (5.0%)	5 (4.3%)			
		Mild	3 (4.0%)	2 (5.0%)	5 (4.3%)	0.7955 [0.1278, 4.9529]	0.8030 [0.1397, 4.6140] 0.8057	-0.0099 [-0.0909, 0.0712]
		Moderate	0	0	0			
		Severe	0	0	0			
	Conjunctivitis allergic		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Corneal epithelium defect		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye pain		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye swelling		1 (1.3%)	0	1 (0.9%)			
		Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Severe	0	0	0			
	Vernal keratoconjunctivitis		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 89 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Vitreous opacities		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Xerophthalmia		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Myopia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Papilloedema		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders			8 (10.7%)	1 (2.5%)	9 (7.8%)			
		Mild	8 (10.7%)	1 (2.5%)	9 (7.8%)	4.6279 [0.5585, 38.3506]	4.2739 [0.5508, 33.1628] 0.1236	0.0817 [-0.0035, 0.1668]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis allergic		2 (2.7%)	1 (2.5%)	3 (2.6%)			
		Mild	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0702 [0.0941, 12.1692]	1.0685 [0.0993, 11.4975] 0.9567	0.0017 [-0.0589, 0.0623]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eczema		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	2.8462 [0.1296, 62.5223]	2.7143 [0.1372, 53.6823] 0.2987	0.0265 [-0.0098, 0.0629]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 91 of 107

Anhang 4-H   Seite 373 von 682

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Dermatitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dyshidrotic eczema		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria chronic		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 92 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Urticaria papular		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		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			
	Rash		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Injury, poisoning and procedural complications			5 (6.7%)	2 (5.0%)	7 (6.1%)			
		Mild	4 (5.3%)	2 (5.0%)	6 (5.2%)	1.0678 [0.1912, 5.9636]	1.0658 [0.2008, 5.6586] 0.9401	0.0033 [-0.0824, 0.0890]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications		Moderate	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Severe	0	0	0			
	Skin laceration		2 (2.7%)	0	2 (1.7%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Severe	0	0	0			
	Animal scratch		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye injury		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 94 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications	Head injury		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Joint injury		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Ligament sprain		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 95 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders			5 (6.7%)	1 (2.5%)	6 (5.2%)			
		Mild	4 (5.3%)	1 (2.5%)	5 (4.3%)	2.2309 [0.2339, 21.2743]	2.1223 [0.2514, 17.9179] 0.4800	0.0281 [-0.0411, 0.0974]
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Severe	0	0	0			
	Granulocytopenia		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]
		Moderate	0	0	0			
		Severe	0	0	0			
	Lymphadenitis		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	2.8462 [0.1296, 62.5223]	2.7143 [0.1372, 53.6823] 0.2987	0.0265 [-0.0098, 0.0629]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 96 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders	Anaemia		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Thymus disorder		1 (1.3%)	0	1 (0.9%)			
		Mild	0	0	0			
		Moderate	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Severe	0	0	0			
	Hypochromic anaemia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 97 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Reproductive system and breast disorders			5 (6.7%)	0	5 (4.3%)			
		Mild	5 (6.7%)	0	5 (4.3%)	3.4287 [0.3972, 29.5949]	3.2380 [0.4017, 26.0984] 0.0977	0.0667 [0.0102, 0.1232]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gynaecomastia		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	2.8481 [0.1309, 61.9810]	2.7381 [0.1372, 54.6396] 0.2963	0.0268 [-0.0098, 0.0633]
		Moderate	0	0	0			
		Severe	0	0	0			
	Balanoposthitis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Reproductive system and breast disorders	Pelvic fluid collection		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Testicular appendage torsion		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
Nervous system disorders			1 (1.3%)	3 (7.5%)	4 (3.5%)			
		Mild	1 (1.3%)	3 (7.5%)	4 (3.5%)	0.1650 [0.0163, 1.6689]	0.1786 [0.0194, 1.6449] 0.0879	-0.0616 [-0.1470, 0.0239]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 99 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Nervous system disorders	Headache		0	3 (7.5%)	3 (2.6%)			
		Mild	0	3 (7.5%)	3 (2.6%)	0.1274 [0.0136, 1.1931]	0.1390 [0.0159, 1.2177] 0.0172	-0.0750 [-0.1566, 0.0066]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dizziness		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
Musculoskeletal and connective tissue disorders			3 (4.0%)	0	3 (2.6%)			
		Mild	3 (4.0%)	0	3 (2.6%)	2.2041 [0.2356, 20.6176]	2.1401 [0.2442, 18.7513] 0.2031	0.0400 [-0.0043, 0.0844]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 100 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Musculoskeletal and connective tissue disorders	Pain in extremity		2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]
		Moderate	0	0	0			
		Severe	0	0	0			
	Arthralgia		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Scoliosis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Cardiac disorders			2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	1.6617 [0.1674, 16.4981]	1.6357 [0.1756, 15.2335] 0.3019	0.0267 [-0.0098, 0.0631]
		Moderate	0	0	0			
		Severe	0	0	0			
	Myocarditis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]
		Moderate	0	0	0			
		Severe	0	0	0			
	Wandering pacemaker		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 102 of 107

Table 1.20 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Congenital, familial and genetic disorders			2 (2.7%)	0	2 (1.7%)			
		Mild	2 (2.7%)	0	2 (1.7%)	2.8481 [0.1309, 61.9810]	2.7381 [0.1372, 54.6396] 0.2963	0.0268 [-0.0098, 0.0633]
		Moderate	0	0	0			
		Severe	0	0	0			
	Buried penis syndrome		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Supernumerary teeth		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 103 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Ear and labyrinth disorders			1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5152 [0.0303, 8.7548]	0.5294 [0.0351, 7.9749] 0.6442	-0.0118 [-0.0662, 0.0426]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cerumen impaction		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Motion sickness		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 104 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Endocrine disorders			1 (1.3%)	1 (2.5%)	2 (1.7%)			
		Mild	1 (1.3%)	1 (2.5%)	2 (1.7%)	0.5250 [0.0312, 8.8227]	0.5366 [0.0352, 8.1698] 0.6520	-0.0116 [-0.0661, 0.0430]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypothyroidism		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Precocious puberty		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 105 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Immune system disorders			0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypersensitivity		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			
	Food allergy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Renal and urinary disorders			0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 106 of 107

Table 1.20 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Renal and urinary disorders	Nocturia		0	1 (2.5%)	1 (0.9%)			
		Mild	0	1 (2.5%)	1 (0.9%)	0.1727 [0.0067, 4.4214]	0.1825 [0.0077, 4.3024] 0.1722	-0.0249 [-0.0733, 0.0234]
		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%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cyanosis		1 (1.3%)	0	1 (0.9%)			
		Mild	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 107 of 107

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Any adverse event			81 (97.6%)	44 (93.6%)	125 (96.2%)				
		Mild	73 (88.0%)	40 (85.1%)	113 (86.9%)	1.2741 [0.4505, 3.6039]	1.0331 [0.8947, 1.1929] 0.6497	0.0282 [-0.0954, 0.1518]	0.9988
		Moderate	7 (8.4%)	4 (8.5%)	11 (8.5%)	0.9887 [0.2741, 3.5670]	0.9897 [0.3061, 3.1998] 0.9863	-0.0009 [-0.1007, 0.0989]	1.0000
		Severe	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
Infections and infestations			50 (60.2%)	31 (66.0%)	81 (62.3%)				
		Mild	47 (56.6%)	28 (59.6%)	75 (57.7%)	0.8586 [0.4046, 1.8222]	0.9421 [0.7041, 1.2604] 0.6938	-0.0346 [-0.2048, 0.1356]	0.8737
		Moderate	2 (2.4%)	3 (6.4%)	5 (3.8%)	0.3575 [0.0577, 2.2145]	0.3738 [0.0653, 2.1382] 0.2535	-0.0403 [-0.1177, 0.0371]	1.0000
		Severe	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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.

v9.4 26MAY2023:14:13 Page 1 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Upper respiratory tract infection		37 (44.6%)	27 (57.4%)	64 (49.2%)				
		Mild	37 (44.6%)	24 (51.1%)	61 (46.9%)	0.7317 [0.3444, 1.5546]	0.8623 [0.6077, 1.2236] 0.4212	-0.0707 [-0.2409, 0.0994]	0.9916
		Moderate	0	3 (6.4%)	3 (2.3%)	0.1348 [0.0144, 1.2583]	0.1457 [0.0166, 1.2805] 0.0194	-0.0643 [-0.1344, 0.0058]	0.9988
		Severe	0	0	0				
	Bronchitis		8 (9.6%)	2 (4.3%)	10 (7.7%)				
		Mild	7 (8.4%)	2 (4.3%)	9 (6.9%)	2.1000 [0.3927, 11.2294]	1.8919 [0.4331, 8.2639] 0.3824	0.0386 [-0.0406, 0.1178]	1.0000
		Moderate	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Severe	0	0	0				0.9990
	Tonsillitis		5 (6.0%)	4 (8.5%)	9 (6.9%)				
		Mild	5 (6.0%)	4 (8.5%)	9 (6.9%)	0.6895 [0.1762, 2.6984]	0.7080 [0.2002, 2.5030] 0.5938	-0.0249 [-0.1199, 0.0700]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 2 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Respiratory tract infection		4 (4.8%)	3 (6.4%)	7 (5.4%)				
		Mild	4 (4.8%)	3 (6.4%)	7 (5.4%)	0.7519 [0.1605, 3.5222]	0.7649 [0.1799, 3.2528] 0.7182	-0.0150 [-0.0986, 0.0686]	0.9985
		Moderate	0	0	0				
		Severe	0	0	0				
	Pneumonia		2 (2.4%)	2 (4.3%)	4 (3.1%)				
		Mild	2 (2.4%)	2 (4.3%)	4 (3.1%)	0.5358 [0.0714, 4.0235]	0.5486 [0.0787, 3.8246] 0.5409	-0.0193 [-0.0854, 0.0469]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasopharyngitis		1 (1.2%)	2 (4.3%)	3 (2.3%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5778 [0.0347, 9.6309]	0.5870 [0.0383, 9.0067] 0.7011	-0.0087 [-0.0558, 0.0384]	0.7283
		Moderate	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	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.

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Otitis media		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1137 [0.0988, 12.5472]	1.1137 [0.0965, 12.8511] 0.9308	0.0024 [-0.0506, 0.0553]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Periodontitis		3 (3.6%)	0	3 (2.3%)				
		Mild	3 (3.6%)	0	3 (2.3%)	2.3198 [0.2490, 21.6113]	2.2554 [0.2564, 19.8407] 0.1884	0.0364 [-0.0039, 0.0766]	0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Rhinitis		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1818 [0.1021, 13.6806]	1.1739 [0.1116, 12.3456] 0.8943	0.0037 [-0.0487, 0.0560]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Herpangina		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	2.8873 [0.1321, 63.1167]	2.7632 [0.1391, 54.9049] 0.2941	0.0234 [-0.0091, 0.0559]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 4 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Laryngitis		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5278 [0.0312, 8.9165]	0.5405 [0.0357, 8.1884] 0.6557	-0.0099 [-0.0571, 0.0372]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Oral herpes		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5568 [0.0338, 9.1798]	0.5568 [0.0329, 9.4317] 0.6808	-0.0093 [-0.0567, 0.0381]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Otitis media acute		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5278 [0.0312, 8.9165]	0.5405 [0.0357, 8.1884] 0.6557	-0.0099 [-0.0571, 0.0372]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Pharyngitis		0	2 (4.3%)	2 (1.5%)				
		Mild	0	2 (4.3%)	2 (1.5%)	0.1815 [0.0183, 1.7959]	0.1912 [0.0205, 1.7878] 0.0595	-0.0426 [-0.1004, 0.0151]	0.9948
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Sinusitis		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Severe	0	0	0				
	Varicella		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5698 [0.0367, 8.8436]	0.5698 [0.0377, 8.6098] 0.6808	-0.0093 [-0.0576, 0.0389]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Abscess limb		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 6 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Bacterial infection		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Chronic sinusitis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Chronic tonsillitis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 7 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Conjunctivitis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9862
		Moderate	0	0	0				
		Severe	0	0	0				
	Folliculitis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastroenteritis		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9819
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 8 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Gastrointestinal bacterial infection		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Hand-foot-and-mouth disease		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Herpes virus infection		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 9 of 148

Table 1.21 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=83) | Daily rhGH (N=47) | Total (N=130) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Hordeolum		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Infectious mononucleosis		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Influenza		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Severe	0	0	0				
	Mumps		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	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.

Table 1.21 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Myringitis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Peritonsillar abscess		0	1 (2.1%)	1 (0.8%)				
		Mild	0	0	0				
		Moderate	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Severe	0	0	0				
	Pulpitis dental		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 11 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Sinobronchitis		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Subcutaneous abscess		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Severe	0	0	0				
	Tonsillitis bacterial		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 12 of 148

Table 1.21 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Tracheitis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Urinary tract infection		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastroenteritis viral		0	0	0				
		Mild	0	0	0				0.9950
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 13 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations			40 (48.2%)	25 (53.2%)	65 (50.0%)				
		Mild	40 (48.2%)	25 (53.2%)	65 (50.0%)	0.8237 [0.4041, 1.6791]	0.9075 [0.6375, 1.2917] 0.5935	-0.0491 [-0.2289, 0.1308]	0.9440
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose increased		14 (16.9%)	14 (29.8%)	28 (21.5%)				
		Mild	14 (16.9%)	14 (29.8%)	28 (21.5%)	0.4726 [0.1986, 1.1248]	0.5746 [0.3042, 1.0855] 0.0899	-0.1259 [-0.2766, 0.0248]	0.5146
		Moderate	0	0	0				
		Severe	0	0	0				
	Insulin-like growth factor increased		25 (30.1%)	3 (6.4%)	28 (21.5%)				
		Mild	25 (30.1%)	3 (6.4%)	28 (21.5%)	6.1903 [1.7700, 21.6503]	4.7035 [1.4899, 14.8483] 0.0017	0.2357 [0.1145, 0.3570]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 14 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Low density lipoprotein increased		4 (4.8%)	4 (8.5%)	8 (6.2%)				
		Mild	4 (4.8%)	4 (8.5%)	8 (6.2%)	0.5433 [0.1297, 2.2754]	0.5601 [0.1432, 2.1911] 0.3992	-0.0372 [-0.1297, 0.0552]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood alkaline phosphatase increased		2 (2.4%)	4 (8.5%)	6 (4.6%)				
		Mild	2 (2.4%)	4 (8.5%)	6 (4.6%)	0.2606 [0.0462, 1.4700]	0.2796 [0.0539, 1.4508] 0.1063	-0.0619 [-0.1484, 0.0246]	0.9984
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood phosphorus increased		4 (4.8%)	1 (2.1%)	5 (3.8%)				
		Mild	4 (4.8%)	1 (2.1%)	5 (3.8%)	2.2846 [0.2553, 20.4472]	2.2499 [0.2630, 19.2497] 0.4447	0.0270 [-0.0357, 0.0898]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 15 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Alanine aminotransferase increased		3 (3.6%)	1 (2.1%)	4 (3.1%)				
		Mild	3 (3.6%)	1 (2.1%)	4 (3.1%)	1.7094 [0.1825, 16.0079]	1.7094 [0.1850, 15.7936] 0.6288	0.0154 [-0.0437, 0.0744]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood iron increased		2 (2.4%)	2 (4.3%)	4 (3.1%)				
		Mild	2 (2.4%)	2 (4.3%)	4 (3.1%)	0.5428 [0.0748, 3.9406]	0.5552 [0.0829, 3.7196] 0.5409	-0.0193 [-0.0860, 0.0475]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood uric acid increased		2 (2.4%)	2 (4.3%)	4 (3.1%)				
		Mild	2 (2.4%)	2 (4.3%)	4 (3.1%)	0.5525 [0.0752, 4.0586]	0.5634 [0.0821, 3.8664] 0.5576	-0.0186 [-0.0851, 0.0479]	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.

v9.4 26MAY2023:14:13 Page 16 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Cortisol decreased		3 (3.6%)	1 (2.1%)	4 (3.1%)				
		Mild	3 (3.6%)	1 (2.1%)	4 (3.1%)	1.7640 [0.1756, 17.7147]	1.7307 [0.1838, 16.2964] 0.6288	0.0154 [-0.0420, 0.0727]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood triglycerides increased		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1134 [0.0989, 12.5294]	1.1103 [0.1062, 11.6112] 0.9308	0.0024 [-0.0506, 0.0554]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Eosinophil count increased		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1470 [0.1003, 13.1136]	1.1438 [0.1039, 12.5904] 0.9130	0.0030 [-0.0496, 0.0557]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 17 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Aspartate aminotransferase increased		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	3.0899 [0.1430, 66.7858]	2.9787 [0.1483, 59.8350] 0.2752	0.0247 [-0.0087, 0.0580]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood urea increased		0	2 (4.3%)	2 (1.5%)				
		Mild	0	2 (4.3%)	2 (1.5%)	0.1097 [0.0051, 2.3734]	0.1191 [0.0059, 2.3934] 0.0630	-0.0420 [-0.0994, 0.0154]	0.9992
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram T wave peaked		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886]	1.7211 [0.1841, 16.0899] 0.2884	0.0240 [-0.0089, 0.0570]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 18 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Tri-iodothyronine free increased		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5278 [0.0312, 8.9165]	0.5405 [0.0357, 8.1884] 0.6557	-0.0099 [-0.0571, 0.0372]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood cholesterol increased		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood lactate dehydrogenase increased		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 19 of 148

Table 1.21 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood potassium increased		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood pressure increased		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		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%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Electrocardiogram ST segment abnormal		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram high voltage		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Haemoglobin decreased		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 21 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Hepatic enzyme abnormal		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Hepatic enzyme increased		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Lipids increased		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 22 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Basophil count increased		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose abnormal		0	0	0				
		Mild	0	0	0				0.9994
		Moderate	0	0	0				
		Severe	0	0	0				
	Liver function test abnormal		0	0	0				
		Mild	0	0	0				0.9950
		Moderate	0	0	0				
		Severe	0	0	0				
	Thyroid function test abnormal		0	0	0				
		Mild	0	0	0				0.9950
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 23 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Thyroxine free decreased		0	0	0				
		Mild	0	0	0				0.9991
		Moderate	0	0	0				
		Severe	0	0	0				
	White blood cell count decreased		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
Respiratory, thoracic and mediastinal disorders			29 (34.9%)	12 (25.5%)	41 (31.5%)				
		Mild	29 (34.9%)	10 (21.3%)	39 (30.0%)	1.9663 [0.8577, 4.5077]	1.6343 [0.8734, 3.0579] 0.1079	0.1348 [-0.0210, 0.2907]	0.9869
		Moderate	0	2 (4.3%)	2 (1.5%)	0.1815 [0.0183, 1.7959]	0.1912 [0.0205, 1.7878] 0.0595	-0.0426 [-0.1004, 0.0151]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Cough		23 (27.7%)	8 (17.0%)	31 (23.8%)				
		Mild	23 (27.7%)	6 (12.8%)	29 (22.3%)	2.5779 [0.9707, 6.8461]	2.1630 [0.9419, 4.9672] 0.0523	0.1481 [0.0119, 0.2842]	0.9991
		Moderate	0	2 (4.3%)	2 (1.5%)	0.1815 [0.0183, 1.7959]	0.1912 [0.0205, 1.7878] 0.0595	-0.0426 [-0.1004, 0.0151]	0.9992
		Severe	0	0	0				
	Rhinorrhoea		4 (4.8%)	4 (8.5%)	8 (6.2%)				
		Mild	4 (4.8%)	4 (8.5%)	8 (6.2%)	0.5433 [0.1297, 2.2754]	0.5601 [0.1432, 2.1911] 0.3992	-0.0372 [-0.1297, 0.0552]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Rhinitis allergic		3 (3.6%)	2 (4.3%)	5 (3.8%)				
		Mild	3 (3.6%)	2 (4.3%)	5 (3.8%)	0.8313 [0.1331, 5.1917]	0.8377 [0.1447, 4.8504] 0.8444	-0.0069 [-0.0771, 0.0632]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Asthma		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1134 [0.0989, 12.5294]	1.1103 [0.1062, 11.6112] 0.9308	0.0024 [-0.0506, 0.0554]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Adenoidal hypertrophy		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Allergic cough		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Nasal obstruction		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Oropharyngeal pain		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Productive cough		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 27 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal congestion		0	0	0				
		Mild	0	0	0				0.9950
		Moderate	0	0	0				
		Severe	0	0	0				
General disorders and administration site conditions			17 (20.5%)	12 (25.5%)	29 (22.3%)				
		Mild	15 (18.1%)	11 (23.4%)	26 (20.0%)	0.7299 [0.3064, 1.7390]	0.7742 [0.3826, 1.5666] 0.4756	-0.0525 [-0.2004, 0.0955]	0.9556

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 28 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions		Moderate	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1134 [0.0989, 12.5294]	1.1103 [0.1062, 11.6112]	0.0024 [-0.0506, 0.0554]	1.0000
							0.9308		
		Severe	0	0	0				
	Pyrexia		13 (15.7%)	7 (14.9%)	20 (15.4%)				
		Mild	12 (14.5%)	6 (12.8%)	18 (13.8%)	1.1598 [0.4054, 3.3182]	1.1381 [0.4523, 2.8635]	0.0175 [-0.1045, 0.1395]	0.9992
							0.7831		
		Moderate	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5278 [0.0312, 8.9165]	0.5405 [0.0357, 8.1884]	-0.0099 [-0.0571, 0.0372]	1.0000
							0.6557		
		Severe	0	0	0				
	Injection site pruritus		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1470 [0.1003, 13.1136]	1.1438 [0.1039, 12.5904]	0.0030 [-0.0496, 0.0557]	1.0000
							0.9130		
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 29 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site erythema		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5698 [0.0367, 8.8436]	0.5698 [0.0377, 8.6098] 0.6808	-0.0093 [-0.0576, 0.0389]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site pain		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886]	1.7211 [0.1841, 16.0899] 0.2884	0.0240 [-0.0089, 0.0570]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site reaction		2 (2.4%)	0	2 (1.5%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site bruising		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site haemorrhage		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site swelling		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 31 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Pain		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Peripheral swelling		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
Gastrointestinal disorders			15 (18.1%)	9 (19.1%)	24 (18.5%)				
		Mild	15 (18.1%)	9 (19.1%)	24 (18.5%)	0.9345 [0.3764, 2.3197]	0.9457 [0.4485, 1.9938] 0.8837	-0.0104 [-0.1513, 0.1304]	0.5889
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Gastrointestinal disorders	Diarrhoea		5 (6.0%)	4 (8.5%)	9 (6.9%)				
		Mild	5 (6.0%)	4 (8.5%)	9 (6.9%)	0.6806 [0.1728, 2.6804]	0.7005 [0.1977, 2.4827] 0.5833	-0.0255 [-0.1201, 0.0691]	0.9959
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyspepsia		2 (2.4%)	2 (4.3%)	4 (3.1%)				
		Mild	2 (2.4%)	2 (4.3%)	4 (3.1%)	0.5690 [0.0784, 4.1310]	0.5782 [0.0855, 3.9086] 0.5712	-0.0180 [-0.0848, 0.0489]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Enteritis		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5278 [0.0312, 8.9165]	0.5405 [0.0357, 8.1884] 0.6557	-0.0099 [-0.0571, 0.0372]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal disorder		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886]	1.7211 [0.1841, 16.0899] 0.2884	0.0240 [-0.0089, 0.0570]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 33 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Abdominal distension		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal pain		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9862
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal pain upper		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Constipation		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 34 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Nausea		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Noninfective gingivitis		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Toothache		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9862
		Moderate	0	0	0				
		Severe	0	0	0				
	Vomiting		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders			10 (12.0%)	8 (17.0%)	18 (13.8%)				
		Mild	10 (12.0%)	8 (17.0%)	18 (13.8%)	0.6773 [0.2505, 1.8307]	0.7084 [0.2934, 1.7105] 0.4388	-0.0492 [-0.1789, 0.0806]	0.9983
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypertriglyceridaemia		7 (8.4%)	2 (4.3%)	9 (6.9%)				
		Mild	7 (8.4%)	2 (4.3%)	9 (6.9%)	2.1053 [0.4147, 10.6886]	2.0092 [0.4304, 9.3791] 0.3637	0.0424 [-0.0404, 0.1252]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypercholesterolaemia		3 (3.6%)	3 (6.4%)	6 (4.6%)				
		Mild	3 (3.6%)	3 (6.4%)	6 (4.6%)	0.5464 [0.1055, 2.8304]	0.5612 [0.1163, 2.7091] 0.4690	-0.0279 [-0.1085, 0.0526]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 36 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders	Decreased appetite		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1137 [0.0988, 12.5472]	1.1137 [0.0965, 12.8511] 0.9308	0.0024 [-0.0506, 0.0553]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Calcium deficiency		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperglycaemia		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 37 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Metabolism and nutrition disorders	Hyperlipidaemia		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperuricaemia		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9979
		Moderate	0	0	0				
		Severe	0	0	0				
Skin and subcutaneous tissue disorders			8 (9.6%)	1 (2.1%)	9 (6.9%)				
		Mild	8 (9.6%)	1 (2.1%)	9 (6.9%)	5.0449 [0.6002, 42.4078]	4.6053 [0.5890, 36.0063] 0.1047	0.0757 [0.0003, 0.1512]	0.5140
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 38 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Dermatitis allergic		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1470 [0.1003, 13.1136]	1.1438 [0.1039, 12.5904] 0.9130	0.0030 [-0.0496, 0.0557]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria		3 (3.6%)	0	3 (2.3%)				
		Mild	3 (3.6%)	0	3 (2.3%)	2.3136 [0.2481, 21.5717]	2.2502 [0.2560, 19.7790] 0.1939	0.0357 [-0.0042, 0.0757]	0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Eczema		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886]	1.7211 [0.1841, 16.0899] 0.2884	0.0240 [-0.0089, 0.0570]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 39 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Dermatitis contact		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyshidrotic eczema		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria papular		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 40 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Rash		0	0	0				
		Mild	0	0	0				0.9950
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria chronic		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
Eye disorders			7 (8.4%)	1 (2.1%)	8 (6.2%)				
		Mild	6 (7.2%)	1 (2.1%)	7 (5.4%)	3.6959 [0.4233, 32.2694]	3.4615 [0.4272, 28.0450] 0.2125	0.0517 [-0.0173, 0.1207]	0.2581
		Moderate	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 41 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Eye disorders	Refraction disorder		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1818 [0.1021, 13.6806]	1.1739 [0.1116, 12.3456] 0.8943	0.0037 [-0.0487, 0.0560]	0.8018
		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%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Corneal epithelium defect		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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.

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Eye disorders	Eye pain		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye swelling		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Severe	0	0	0				
	Myopia		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Xerophthalmia		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 43 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI][b]	RR [95 %-CI][b] p-value[c]	RD [95 %-CI][b]	
Eye disorders	Papilloedema		0	0	0				
		Mild	0	0	0				1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Vernal keratoconjunctivitis		0	0	0				
		Mild	0	0	0				0.9950
		Moderate	0	0	0				
		Severe	0	0	0				
	Vitreous opacities		0	0	0				
		Mild	0	0	0				0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
Injury, poisoning and procedural complications			5 (6.0%)	2 (4.3%)	7 (5.4%)				
		Mild	4 (4.8%)	2 (4.3%)	6 (4.6%)	1.1284 [0.2046, 6.2230]	1.1250 [0.2156, 5.8707] 0.8885	0.0054 [-0.0698, 0.0806]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Injury, poisoning and procedural complications		Moderate	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Severe	0	0	0				
	Head injury		1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5698 [0.0367, 8.8436]	0.5698 [0.0377, 8.6098] 0.6808	-0.0093 [-0.0576, 0.0389]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Skin laceration		2 (2.4%)	0	2 (1.5%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Injury, poisoning and procedural complications	Animal scratch		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye injury		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Joint injury		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Ligament sprain		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.

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Blood and lymphatic system disorders			5 (6.0%)	1 (2.1%)	6 (4.6%)				
		Mild	4 (4.8%)	1 (2.1%)	5 (3.8%)	2.2965 [0.2434, 21.6703]	2.1914 [0.2602, 18.4575] 0.4599	0.0258 [-0.0353, 0.0869]	0.9695
		Moderate	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Severe	0	0	0				
	Granulocytopenia		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886]	1.7211 [0.1841, 16.0899] 0.2884	0.0240 [-0.0089, 0.0570]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Lymphadenitis		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	2.8873 [0.1321, 63.1167]	2.7632 [0.1391, 54.9049] 0.2941	0.0234 [-0.0091, 0.0559]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 47 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Blood and lymphatic system disorders	Anaemia		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9442
		Moderate	0	0	0				
		Severe	0	0	0				
	Thymus disorder		1 (1.2%)	0	1 (0.8%)				
		Mild	0	0	0				
		Moderate	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Severe	0	0	0				
	Hypochromic anaemia		0	0	0				
		Mild	0	0	0				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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Nervous system disorders			2 (2.4%)	4 (8.5%)	6 (4.6%)				
		Mild	2 (2.4%)	4 (8.5%)	6 (4.6%)	0.2614 [0.0445, 1.5355]	0.2935 [0.0575, 1.4971] 0.1185	-0.0594 [-0.1443, 0.0255]	0.9919
		Moderate	0	0	0				
		Severe	0	0	0				
	Dizziness		2 (2.4%)	1 (2.1%)	3 (2.3%)				
		Mild	2 (2.4%)	1 (2.1%)	3 (2.3%)	1.1818 [0.1021, 13.6806]	1.1739 [0.1116, 12.3456] 0.8943	0.0037 [-0.0487, 0.0560]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Headache		0	3 (6.4%)	3 (2.3%)				
		Mild	0	3 (6.4%)	3 (2.3%)	0.0753 [0.0037, 1.5168]	0.0851 [0.0046, 1.5875] 0.0219	-0.0630 [-0.1325, 0.0065]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 49 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Musculoskelet al and connective tissue disorders			5 (6.0%)	0	5 (3.8%)				
		Mild	5 (6.0%)	0	5 (3.8%)	3.3157 [0.3720, 29.5530]	3.1429 [0.3739, 26.4197] 0.0839	0.0610 [0.0095, 0.1125]	0.9992
		Moderate	0	0	0				
		Severe	0	0	0				
	Arthralgia		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	3.0899 [0.1430, 66.7858]	2.9787 [0.1483, 59.8350] 0.2752	0.0247 [-0.0087, 0.0580]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain in extremity		2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886]	1.7211 [0.1841, 16.0899] 0.2884	0.0240 [-0.0089, 0.0570]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 50 of 148

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Musculoskeletal and connective tissue disorders	Scoliosis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
Reproductive system and breast disorders			3 (3.6%)	0	3 (2.3%)				
		Mild	3 (3.6%)	0	3 (2.3%)	2.3198 [0.2490, 21.6113]	2.2554 [0.2564, 19.8407] 0.1884	0.0364 [-0.0039, 0.0766]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Gynaecomastia		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Reproductive system and breast disorders	Pelvic fluid collection		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Testicular appendage torsion		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Balanoposthitis		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.

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Cardiac disorders			2 (2.4%)	0	2 (1.5%)				
		Mild	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886]	1.7211 [0.1841, 16.0899] 0.2884	0.0240 [-0.0089, 0.0570]	0.9993
		Moderate	0	0	0				
		Severe	0	0	0				
	Myocarditis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Wandering pacemaker		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Ear and labyrinth disorders			1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5278 [0.0312, 8.9165]	0.5405 [0.0357, 8.1884] 0.6557	-0.0099 [-0.0571, 0.0372]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Cerumen impaction		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Motion sickness		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Immune system disorders			1 (1.2%)	1 (2.1%)	2 (1.5%)				
		Mild	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5698 [0.0367, 8.8436]	0.5698 [0.0377, 8.6098] 0.6808	-0.0093 [-0.0576, 0.0389]	1.0000
		Moderate	0	0	0				
		Severe	0	0	0				
	Food allergy		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypersensitivity		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 55 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Congenital, familial and genetic disorders			1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Supernumerary teeth		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Buried penis syndrome		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 56 of 148

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Endocrine disorders			1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9842
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypothyroidism		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
		Moderate	0	0	0				
		Severe	0	0	0				
	Precocious puberty		0	0	0				
		Mild	0	0	0				0.9950
		Moderate	0	0	0				
		Severe	0	0	0				

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

Table 1.21 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

						Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Renal and urinary disorders			0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Nocturia		0	1 (2.1%)	1 (0.8%)				
		Mild	0	1 (2.1%)	1 (0.8%)	0.1900 [0.0075, 4.8310]	0.1986 [0.0084, 4.7099] 0.1918	-0.0210 [-0.0620, 0.0200]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
Vascular disorders			1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 58 of 148

Table 1.21 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

| | | | | | | Lonapegsomatropin vs. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=83)	Daily rhGH (N=47)	Total (N=130)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Vascular disorders	Cyanosis		1 (1.2%)	0	1 (0.8%)				
		Mild	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 59 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Any adverse event			14 (100.0%)	5 (100.0%)	19 (100.0%)			
		Mild	13 (92.9%)	5 (100.0%)	18 (94.7%)	0.6000 [0.0172, 20.9812]	0.8000 [0.5161, 1.2400] 0.5271	-0.0777 [-0.2177, 0.0623]
		Moderate	0	0	0			
		Severe	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
Infections and infestations			10 (71.4%)	4 (80.0%)	14 (73.7%)			
		Mild	9 (64.3%)	4 (80.0%)	13 (68.4%)	0.4375 [0.0330, 5.8025]	0.8171 [0.4693, 1.4225] 0.5494	-0.1456 [-0.5555, 0.2642]
		Moderate	0	0	0			
		Severe	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Upper respiratory tract infection		7 (50.0%)	3 (60.0%)	10 (52.6%)			
		Mild	7 (50.0%)	3 (60.0%)	10 (52.6%)	0.7000 [0.0975, 5.0252]	0.8361 [0.3199, 2.1849] 0.7239	-0.0971 [-0.6269, 0.4327]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasopharyngitis		1 (7.1%)	2 (40.0%)	3 (15.8%)			
		Mild	1 (7.1%)	2 (40.0%)	3 (15.8%)	0.1081 [0.0054, 2.1531]	0.1951 [0.0254, 1.4992] 0.1047	-0.3204 [-0.7639, 0.1231]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastroenteritis		1 (7.1%)	1 (20.0%)	2 (10.5%)			
		Mild	1 (7.1%)	1 (20.0%)	2 (10.5%)	0.2500 [0.0073, 8.5598]	0.4000 [0.0428, 3.7375] 0.4624	-0.1165 [-0.4570, 0.2240]
		Moderate	0	0	0			
		Severe	0	0	0			
	Bronchitis		1 (7.1%)	0	1 (5.3%)			
		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 61 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Bronchitis	Severe	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
	Conjunctivitis		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastroenteritis viral		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hand-foot-and-mouth disease		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Herpangina		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngitis		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			
	Respiratory tract infection		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Tonsillitis		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Abscess limb		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Bacterial infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Chronic sinusitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Chronic tonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Folliculitis		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.

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Gastrointestinal bacterial infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpes virus 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			
	Infectious mononucleosis		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 65 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Laryngitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Mumps		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Myringitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Oral herpes		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis media		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 66 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Otitis media acute		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Periodontitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Peritonsillar abscess		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 67 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Rhinitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinobronchitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinusitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Subcutaneous abscess		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tonsillitis bacterial		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 68 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Tracheitis		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			
Investigations			9 (64.3%)	3 (60.0%)	12 (63.2%)			
		Mild	9 (64.3%)	3 (60.0%)	12 (63.2%)	1.2571 [0.1670, 9.4648]	1.0968 [0.4774, 2.5198] 0.8127	0.0583 [-0.4602, 0.5767]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Blood glucose increased		2 (14.3%)	3 (60.0%)	5 (26.3%)			
		Mild	2 (14.3%)	3 (60.0%)	5 (26.3%)	0.0886 [0.0064, 1.2176]	0.2258 [0.0520, 0.9797] 0.0477	-0.4660 [-0.9196, -0.0124]
		Moderate	0	0	0			
		Severe	0	0	0			
	Insulin-like growth factor increased		4 (28.6%)	0	4 (21.1%)			
		Mild	4 (28.6%)	0	4 (21.1%)	2.9341 [0.2579, 33.3748]	2.1964 [0.3069, 15.7212] 0.1514	0.3010 [0.0629, 0.5390]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose abnormal		1 (7.1%)	2 (40.0%)	3 (15.8%)			
		Mild	1 (7.1%)	2 (40.0%)	3 (15.8%)	0.1905 [0.0189, 1.9234]	0.1905 [0.0195, 1.8590] 0.1000	-0.3301 [-0.8170, 0.1568]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Basophil count increased		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood alkaline phosphatase increased		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood uric acid increased		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 71 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Eosinophil count increased		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			
	Liver function test abnormal		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroid function test abnormal		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 72 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	White blood cell count decreased		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		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			
	Aspartate aminotransferase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood cholesterol 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood iron increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood lactate dehydrogenase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood phosphorus increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood potassium 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 74 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood pressure 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			
	Blood triglycerides increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood urea 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 75 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Cortisol decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram ST segment abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram T wave peaked		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram high voltage		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 76 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Haemoglobin decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Lipids 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 77 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Low density lipoprotein increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroxine free decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tri-iodothyronine free 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 78 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders			4 (28.6%)	1 (20.0%)	5 (26.3%)			
		Mild	4 (28.6%)	1 (20.0%)	5 (26.3%)	1.5510 [0.1446, 16.6364]	1.4286 [0.2011, 10.1468] 0.7194	0.0874 [-0.3559, 0.5306]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cough		4 (28.6%)	0	4 (21.1%)			
		Mild	4 (28.6%)	0	4 (21.1%)	2.8591 [0.2649, 30.8587]	2.2456 [0.3207, 15.7246] 0.1942	0.2913 [0.0537, 0.5288]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal congestion		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Allergic cough		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Asthma		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal obstruction		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Oropharyngeal 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Productive cough		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			
	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 81 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Eye disorders			2 (14.3%)	2 (40.0%)	4 (21.1%)			
		Mild	2 (14.3%)	2 (40.0%)	4 (21.1%)	0.3500 [0.0507, 2.4142]	0.3500 [0.0450, 2.7250] 0.2605	-0.2524 [-0.7738, 0.2689]
		Moderate	0	0	0			
		Severe	0	0	0			
	Refraction disorder		1 (7.1%)	1 (20.0%)	2 (10.5%)			
		Mild	1 (7.1%)	1 (20.0%)	2 (10.5%)	0.3500 [0.0216, 5.6698]	0.3500 [0.0192, 6.3761] 0.4581	-0.1262 [-0.5160, 0.2636]
		Moderate	0	0	0			
		Severe	0	0	0			
	Vernal keratoconjunctivitis		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
		Moderate	0	0	0			
		Severe	0	0	0			
	Vitreous opacities		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 82 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Conjunctivitis allergic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Corneal epithelium defect		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye pain		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			
	Myopia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 83 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Papilloedema		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Xerophthalmia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Gastrointestinal disorders			2 (14.3%)	2 (40.0%)	4 (21.1%)			
		Mild	2 (14.3%)	2 (40.0%)	4 (21.1%)	0.2569 [0.0253, 2.6048]	0.3415 [0.0579, 2.0131] 0.2368	-0.2621 [-0.7371, 0.2129]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal pain		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 84 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Abdominal pain upper		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Diarrhoea		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Toothache		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal distension		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Constipation		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			
	Enteritis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastrointestinal 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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 86 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Noninfective gingivitis		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			
General disorders and administration site conditions			3 (21.4%)	1 (20.0%)	4 (21.1%)			
		Mild	3 (21.4%)	1 (20.0%)	4 (21.1%)	1.0500 [0.1051, 10.4859]	1.0500 [0.1007, 10.9501] 0.9650	0.0097 [-0.4445, 0.4640]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pyrexia		3 (21.4%)	1 (20.0%)	4 (21.1%)			
		Mild	3 (21.4%)	1 (20.0%)	4 (21.1%)	1.0500 [0.1051, 10.4859]	1.0500 [0.1007, 10.9501] 0.9650	0.0097 [-0.4445, 0.4640]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 87 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site pain		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site bruising		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site erythema		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site haemorrhage		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 88 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site pruritus		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site reaction		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site swelling		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Peripheral 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders			2 (14.3%)	1 (20.0%)	3 (15.8%)			
		Mild	2 (14.3%)	1 (20.0%)	3 (15.8%)	0.7619 [0.0698, 8.3160]	0.7619 [0.0756, 7.6809] 0.8058	-0.0485 [-0.4890, 0.3919]
		Moderate	0	0	0			
		Severe	0	0	0			
	Rash		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria chronic		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 90 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Urticaria papular		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		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			
	Urticaria		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Endocrine disorders			1 (7.1%)	1 (20.0%)	2 (10.5%)			
		Mild	1 (7.1%)	1 (20.0%)	2 (10.5%)	0.2500 [0.0104, 5.9847]	0.3333 [0.0289, 3.8416] 0.3918	-0.1359 [-0.4999, 0.2281]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Endocrine disorders	Hypothyroidis m		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Precocious puberty		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0877 [0.0027, 2.8779]	0.1333 [0.0068, 2.6334] 0.0833	-0.2039 [-0.5563, 0.1485]
		Moderate	0	0	0			
		Severe	0	0	0			
Reproductive system and breast disorders			2 (14.3%)	0	2 (10.5%)			
		Mild	2 (14.3%)	0	2 (10.5%)	1.4275 [0.1208, 16.8721]	1.3467 [0.1693, 10.7131] 0.3919	0.1456 [-0.0392, 0.3305]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 93 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Reproductive system and breast disorders	Balanoposthitis		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gynaecomastia		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pelvic fluid collection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Testicular appendage torsion		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Congenital, familial and genetic disorders			1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Buried penis syndrome		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Supernumerary teeth		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications			1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Ligament sprain		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.2353 [0.0398, 38.3004]	1.2000 [0.0608, 23.7007] 0.5637	0.0680 [-0.0644, 0.2003]
		Moderate	0	0	0			
		Severe	0	0	0			
	Animal scratch		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications	Head injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Joint injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Skin laceration		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Metabolism and nutrition disorders			1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 97 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Hyperuricaemia		1 (7.1%)	0	1 (5.3%)			
		Mild	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]
		Moderate	0	0	0			
		Severe	0	0	0			
	Calcium deficiency		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Decreased appetite		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypercholesterolaemia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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)

			TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
System Organ Class	Preferred Term	Severity				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Hyperglycaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperlipidaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypertriglyceridaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Nervous system disorders			0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 99 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Nervous system disorders	Headache		0	1 (20.0%)	1 (5.3%)			
		Mild	0	1 (20.0%)	1 (5.3%)	0.0909 [0.0023, 3.5851]	0.1667 [0.0093, 2.9839] 0.1138	-0.1942 [-0.5422, 0.1539]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dizziness		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Blood and lymphatic system disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Anaemia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 100 of 148

Anhang 4-H   Seite 489 von 682

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders	Granulocytope nia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypochromic anaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Lymphadenitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thymus 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 101 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Cardiac disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Myocarditis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Wandering pacemaker		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			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 102 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Ear and labyrinth disorders	Cerumen impaction		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Motion sickness		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			
	Food allergy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypersensitivity		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 103 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Musculoskeletal and connective tissue disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Arthralgia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain in extremity		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Scoliosis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 104 of 148

Table 1.21 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)

System Organ Class	Preferred Term	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Renal and urinary disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Nocturia		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			
		Severe	0	0	0			
	Cyanosis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 105 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Any adverse event			3 (100.0%)	1 (100.0%)	4 (100.0%)			
		Mild	3 (100.0%)	1 (100.0%)	4 (100.0%)			
		Moderate	0	0	0			
		Severe	0	0	0			
Blood and lymphatic system disorders			1 (33.3%)	1 (100.0%)	2 (50.0%)			
		Mild	1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
		Moderate	0	0	0			
		Severe	0	0	0			
	Anaemia		0	1 (100.0%)	1 (25.0%)			
		Mild	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 106 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders	Hypochromic anaemia		1 (33.3%)	0	1 (25.0%)			
		Mild	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]
		Moderate	0	0	0			
		Severe	0	0	0			
	Granulocytopenia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Lymphadenitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thymus 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 107 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders			1 (33.3%)	1 (100.0%)	2 (50.0%)			
		Mild	1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
		Moderate	0	0	0			
		Severe	0	0	0			
	Papilloedema		1 (33.3%)	1 (100.0%)	2 (50.0%)			
		Mild	1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
		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			
	Corneal epithelium defect		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 108 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Eye pain		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			
	Myopia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Refraction disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vernal keratoconjunctivitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 109 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Vitreous opacities		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Xerophthalmia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Investigations			1 (33.3%)	1 (100.0%)	2 (50.0%)			
		Mild	1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose increased		1 (33.3%)	1 (100.0%)	2 (50.0%)			
		Mild	1 (33.3%)	1 (100.0%)	2 (50.0%)	0.2000 [0.0045, 8.8249]	0.3333 [0.0673, 1.6515] 0.3173	-0.6667 [-1.0000, -0.1332]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 110 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Thyroxine free decreased		1 (33.3%)	0	1 (25.0%)			
		Mild	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]
		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			
	Aspartate 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.

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Basophil count increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood alkaline phosphatase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood cholesterol increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose abnormal		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood iron increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood lactate dehydrogenase increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood phosphorus increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood potassium 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 113 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood pressure 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			
	Blood triglycerides increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood urea 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 114 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood uric acid increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cortisol decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram ST segment abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram T wave peaked		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Electrocardiogram high voltage		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			
	Haemoglobin decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme abnormal		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 116 of 148

Table 1.21 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. Daily rhGH [a] | | |
| | | | TransCon hGH (N=3) | Daily rhGH (N=1) | Total (N=4) | OR [95 %-CI] [b] | RR [95 %-CI] [b] p-value[c] | RD [95 %-CI] [b] |
System Organ Class	Preferred Term	Severity						
Investigations	Hepatic enzyme 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			
	Lipids increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Liver function test abnormal		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 117 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Low density lipoprotein increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroid function test abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tri-iodothyronine free 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 118 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI][b]	RR [95 %-CI][b] p-value[c]	RD [95 %-CI][b]
						Lonapegsomatropin vs. Daily rhGH [a]		
Gastrointestinal disorders			0	1 (100.0%)	1 (25.0%)			
		Mild	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
		Moderate	0	0	0			
		Severe	0	0	0			
	Diarrhoea		0	1 (100.0%)	1 (25.0%)			
		Mild	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal distension		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 119 of 148

Anhang 4-H   Seite 508 von 682

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Abdominal pain upper		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			
	Dyspepsia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Enteritis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastrointestinal 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 120 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Nausea		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Noninfective gingivitis		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			
	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders			1 (33.3%)	0	1 (25.0%)			
		Mild	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperuricaemia		1 (33.3%)	0	1 (25.0%)			
		Mild	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]
		Moderate	0	0	0			
		Severe	0	0	0			
	Calcium deficiency		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Decreased appetite		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 122 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Hypercholesterolaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperglycaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperlipidaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypertriglyceridaemia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Nervous system disorders			0	1 (100.0%)	1 (25.0%)			
		Mild	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
		Moderate	0	0	0			
		Severe	0	0	0			
	Headache		0	1 (100.0%)	1 (25.0%)			
		Mild	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dizziness		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Cardiac disorders	Myocarditis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Wandering pacemaker		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Congenital, familial and genetic disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Buried penis 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 125 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Congenital, familial and genetic disorders	Supernumerary teeth		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			
		Severe	0	0	0			
	Cerumen impaction		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Motion sickness		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 126 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Endocrine disorders			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			
	Precocious puberty		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
General disorders and administration site conditions			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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 127 of 148

Table 1.21 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

| | | | TransCon hGH (N=3) | Daily rhGH (N=1) | Total (N=4) | Lonapegsomatropin vs. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site bruising		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site erythema		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site haemorrhage		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 128 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site pruritus		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site reaction		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site swelling		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Peripheral 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 129 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Pyrexia		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			
	Food allergy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypersensitivity		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Abscess limb		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Bacterial infection		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			
	Chronic sinusitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 131 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Chronic tonsillitis		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			
	Folliculitis		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 132 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Gastrointestinal bacterial infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hand-foot-and-mouth disease		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpangina		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpes virus 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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 133 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Infectious mononucleosis		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		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Mumps		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Myringitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 134 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Nasopharyngitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Oral herpes		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis media		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			
	Periodontitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 135 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Peritonsillar abscess		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pharyngitis		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			
	Respiratory tract 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 136 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Rhinitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinobronchitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinusitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Subcutaneous abscess		0	0	0			
		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 137 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Tonsillitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tracheitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Upper respiratory tract infection		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 138 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Animal scratch		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye injury		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			
	Joint 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 139 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications	Ligament sprain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Skin laceration		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Musculoskeletal and connective tissue disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Arthralgia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 140 of 148

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Musculoskeletal and connective tissue disorders	Pain in extremity		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Scoliosis		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			
	Nocturia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Reproductive system and breast disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Balanoposthitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gynaecomastia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pelvic fluid collection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Testicular appendage torsion		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Adenoidal hypertrophy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Allergic cough		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Asthma		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cough		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Nasal congestion		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal obstruction		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Oropharyngeal pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Productive cough		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			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 144 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		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			
Skin and subcutaneous tissue disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 145 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	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			
	Dyshidrotic eczema		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Urticaria		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria chronic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria papular		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			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 147 of 148

Table 1.21 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=3)	Daily rhGH (N=1)	Total (N=4)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Vascular disorders	Cyanosis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 148 of 148

Table 1.22 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=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Any adverse event			69 (97.2%)	36 (94.7%)	105 (96.3%)				
		Mild	62 (87.3%)	34 (89.5%)	96 (88.1%)	0.8117 [0.2333, 2.8241]	0.9760 [0.8476, 1.1239] 0.7443	-0.0214 [-0.1463, 0.1034]	0.2213
		Moderate	6 (8.5%)	2 (5.3%)	8 (7.3%)	1.6587 [0.3190, 8.6235]	1.6044 [0.3408, 7.5538] 0.5468	0.0319 [-0.0644, 0.1281]	0.1965
		Severe	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9982
Infections and infestations			45 (63.4%)	23 (60.5%)	68 (62.4%)				
		Mild	42 (59.2%)	21 (55.3%)	63 (57.8%)	1.1697 [0.5117, 2.6739]	1.0642 [0.7630, 1.4843] 0.7119	0.0355 [-0.1523, 0.2234]	0.1223
		Moderate	2 (2.8%)	2 (5.3%)	4 (3.7%)	0.5174 [0.0698, 3.8381]	0.5319 [0.0782, 3.6173] 0.5167	-0.0247 [-0.1054, 0.0560]	0.9768
		Severe	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9982

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 1 of 106

Anhang 4-H   Seite 538 von 682

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Infections and infestations	Upper respiratory tract infection		32 (45.1%)	20 (52.6%)	52 (47.7%)				
		Mild	32 (45.1%)	18 (47.4%)	50 (45.9%)	0.8910 [0.3906, 2.0327]	0.9446 [0.6309, 1.4144] 0.7867	-0.0263 [-0.2145, 0.1619]	0.3862
		Moderate	0	2 (5.3%)	2 (1.8%)	0.1698 [0.0170, 1.6934]	0.1818 [0.0196, 1.6874] 0.0525	-0.0528 [-0.1238, 0.0183]	0.9995
		Severe	0	0	0				
	Bronchitis		7 (9.9%)	2 (5.3%)	9 (8.3%)				
		Mild	6 (8.5%)	2 (5.3%)	8 (7.3%)	1.7143 [0.2978, 9.8693]	1.5556 [0.3597, 6.7273] 0.5481	0.0296 [-0.0602, 0.1193]	0.9799
		Moderate	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Severe	0	0	0				0.9724
	Tonsillitis		4 (5.6%)	2 (5.3%)	6 (5.5%)				
		Mild	4 (5.6%)	2 (5.3%)	6 (5.5%)	1.0765 [0.1891, 6.1275]	1.0725 [0.2061, 5.5812] 0.9341	0.0038 [-0.0855, 0.0931]	0.5607
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Respiratory tract infection		4 (5.6%)	1 (2.6%)	5 (4.6%)				
		Mild	4 (5.6%)	1 (2.6%)	5 (4.6%)	2.3000 [0.2423, 21.8333]	2.1818 [0.2582, 18.4355] 0.4605	0.0309 [-0.0422, 0.1040]	0.1862
		Moderate	0	0	0				
		Severe	0	0	0				
	Herpangina		3 (4.2%)	0	3 (2.8%)				
		Mild	3 (4.2%)	0	3 (2.8%)	4.1429 [0.1995, 86.0474]	3.7500 [0.2072, 67.8853] 0.2007	0.0414 [-0.0050, 0.0878]	0.9773
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasopharyngitis		1 (1.4%)	2 (5.3%)	3 (2.8%)				
		Mild	1 (1.4%)	2 (5.3%)	3 (2.8%)	0.2558 [0.0220, 2.9788]	0.2727 [0.0261, 2.8550] 0.2483	-0.0380 [-0.1136, 0.0375]	0.7278
		Moderate	0	0	0				0.9750
		Severe	0	0	0				
	Otitis media		2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0554 [0.0945, 11.7881]	1.0554 [0.0931, 11.9639] 0.9650	0.0014 [-0.0629, 0.0658]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 3 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Pneumonia		2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0400 [0.0860, 12.5721]	1.0370 [0.1027, 10.4689] 0.9757	0.0010 [-0.0613, 0.0633]	0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Rhinitis		2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0952 [0.0942, 12.7391]	1.0909 [0.1042, 11.4201] 0.9425	0.0024 [-0.0609, 0.0657]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				
	Laryngitis		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5000 [0.0289, 8.6494]	0.5185 [0.0350, 7.6815] 0.6321	-0.0128 [-0.0699, 0.0443]	0.9988
		Moderate	0	0	0				
		Severe	0	0	0				
	Oral herpes		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5277 [0.0323, 8.6275]	0.5277 [0.0319, 8.7405] 0.6499	-0.0123 [-0.0704, 0.0457]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 4 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Periodontitis		2 (2.8%)	0	2 (1.8%)				
		Mild	2 (2.8%)	0	2 (1.8%)	1.6656 [0.1672, 16.5962]	1.6364 [0.1763, 15.1865] 0.3023	0.0281 [-0.0104, 0.0665]	0.9995
		Moderate	0	0	0				
		Severe	0	0	0				
	Pharyngitis		0	2 (5.3%)	2 (1.8%)				
		Mild	0	2 (5.3%)	2 (1.8%)	0.1698 [0.0170, 1.6934]	0.1818 [0.0196, 1.6874] 0.0525	-0.0528 [-0.1238, 0.0183]	0.9430
		Moderate	0	0	0				
		Severe	0	0	0				
	Varicella		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5359 [0.0343, 8.3837]	0.5359 [0.0347, 8.2752] 0.6499	-0.0123 [-0.0710, 0.0463]	0.9988
		Moderate	0	0	0				
		Severe	0	0	0				
	Abscess limb		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 5 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Bacterial infection		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Chronic sinusitis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Chronic tonsillitis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 6 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Conjunctivitis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9590
		Moderate	0	0	0				
		Severe	0	0	0				
	Folliculitis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastroenteritis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9499
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 7 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Gastroenteritis viral		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Hand-foot-and-mouth disease		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Herpes virus infection		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 8 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Hordeolum		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Infectious mononucleosis		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Influenza		1 (1.4%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 9 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Otitis media acute		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9590
		Moderate	0	0	0				
		Severe	0	0	0				
	Pulpitis dental		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Sinobronchitis		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Sinusitis		0	1 (2.6%)	1 (0.9%)				
		Mild	0	0	0				0.9724

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 10 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Sinusitis	Moderate	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	−0.0261 [−0.0769, 0.0246]	0.9738
		Severe	0	0	0				
	Subcutaneous abscess		1 (1.4%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [−0.0133, 0.0409]	0.9804
		Severe	0	0	0				
	Tonsillitis bacterial		1 (1.4%)	0	1 (0.9%)				
		Mild	0	0	0				
		Moderate	0	0	0				
		Severe	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [−0.0133, 0.0418]	0.9804
	Tracheitis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [−0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 11 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Urinary tract infection		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Gastrointestinal bacterial infection		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				
	Mumps		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				
	Myringitis		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 12 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Infections and infestations	Peritonsillar abscess		0	0	0				
		Mild	0	0	0				
		Moderate	0	0	0				0.9750
		Severe	0	0	0				
Investigations			34 (47.9%)	22 (57.9%)	56 (51.4%)				
		Mild	34 (47.9%)	22 (57.9%)	56 (51.4%)	0.6758 [0.3086, 1.4800]	0.8269 [0.5708, 1.1978] 0.3238	-0.1001 [-0.2981, 0.0980]	0.3250
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose increased		11 (15.5%)	13 (34.2%)	24 (22.0%)				
		Mild	11 (15.5%)	13 (34.2%)	24 (22.0%)	0.3478 [0.1361, 0.8890]	0.4556 [0.2278, 0.9111] 0.0257	-0.1858 [-0.3571, -0.0145]	0.6475
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 13 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Insulin-like growth factor increased		21 (29.6%)	3 (7.9%)	24 (22.0%)				
		Mild	21 (29.6%)	3 (7.9%)	24 (22.0%)	4.8139 [1.3483, 17.1876]	3.7252 [1.1812, 11.7484] 0.0093	0.2150 [0.0783, 0.3518]	0.9760
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood uric acid increased		3 (4.2%)	2 (5.3%)	5 (4.6%)				
		Mild	3 (4.2%)	2 (5.3%)	5 (4.6%)	0.7937 [0.1272, 4.9539]	0.8022 [0.1404, 4.5827] 0.8058	-0.0104 [-0.0956, 0.0747]	0.9996
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood alkaline phosphatase increased		1 (1.4%)	3 (7.9%)	4 (3.7%)				
		Mild	1 (1.4%)	3 (7.9%)	4 (3.7%)	0.1735 [0.0182, 1.6572]	0.1797 [0.0195, 1.6595] 0.0874	-0.0651 [-0.1558, 0.0256]	0.2900
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 14 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood phosphorus increased		3 (4.2%)	1 (2.6%)	4 (3.7%)				
		Mild	3 (4.2%)	1 (2.6%)	4 (3.7%)	1.6078 [0.1701, 15.1986]	1.6078 [0.1713, 15.0887] 0.6713	0.0162 [-0.0546, 0.0870]	0.9760
		Moderate	0	0	0				
		Severe	0	0	0				
	Low density lipoprotein increased		2 (2.8%)	2 (5.3%)	4 (3.7%)				
		Mild	2 (2.8%)	2 (5.3%)	4 (3.7%)	0.5174 [0.0698, 3.8381]	0.5319 [0.0782, 3.6173] 0.5167	-0.0247 [-0.1054, 0.0560]	0.9564
		Moderate	0	0	0				
		Severe	0	0	0				
	Alanine aminotransferase increased		3 (4.2%)	0	3 (2.8%)				
		Mild	3 (4.2%)	0	3 (2.8%)	4.1325 [0.2047, 83.4175]	3.8889 [0.2092, 72.2910] 0.1940	0.0428 [-0.0043, 0.0898]	0.9500
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 15 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Blood iron increased		2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0566 [0.0923, 12.0999]	1.0545 [0.1012, 10.9839] 0.9650	0.0014 [-0.0622, 0.0651]	0.9776
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood triglycerides increased		2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0566 [0.0923, 12.0999]	1.0545 [0.1012, 10.9839] 0.9650	0.0014 [-0.0622, 0.0651]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				
	Cortisol decreased		3 (4.2%)	0	3 (2.8%)				
		Mild	3 (4.2%)	0	3 (2.8%)	2.2116 [0.2357, 20.7512]	2.1398 [0.2449, 18.6924] 0.2023	0.0423 [-0.0045, 0.0892]	0.9500
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 16 of 106

Table 1.22 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. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Eosinophil count increased		2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0749 [0.0943, 12.2577]	1.0732 [0.0985, 11.6866] 0.9540	0.0019 [-0.0619, 0.0657]	0.9772
		Moderate	0	0	0				
		Severe	0	0	0				
	Aspartate aminotransferase increased		2 (2.8%)	0	2 (1.8%)				
		Mild	2 (2.8%)	0	2 (1.8%)	2.8824 [0.1329, 62.5149]	2.7778 [0.1387, 55.6118] 0.2926	0.0285 [-0.0102, 0.0672]	0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood glucose abnormal		0	2 (5.3%)	2 (1.8%)				
		Mild	0	2 (5.3%)	2 (1.8%)	0.1011 [0.0047, 2.1968]	0.1111 [0.0055, 2.2245] 0.0537	-0.0523 [-0.1231, 0.0185]	0.9430
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 17 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Tri-iodothyronine free increased		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5000 [0.0289, 8.6494]	0.5185 [0.0350, 7.6815] 0.6321	-0.0128 [-0.0699, 0.0443]	0.9988
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood cholesterol increased		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood urea increased		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9984
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 18 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Electrocardiogram ST segment abnormal		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Haemoglobin decreased		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Hepatic enzyme abnormal		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 19 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Hepatic enzyme increased		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Lipids increased		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Liver function test abnormal		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 20 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Investigations	Thyroid function test abnormal		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Thyroxine free decreased		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	White blood cell count decreased		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Basophil count increased		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood lactate dehydrogenase increased		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood potassium increased		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
	Blood pressure increased		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 22 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Investigations	Blood thyroid stimulating hormone increased		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram T wave peaked		0	0	0				
		Mild	0	0	0				0.9740
		Moderate	0	0	0				
		Severe	0	0	0				
	Electrocardiogram high voltage		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 23 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Respiratory, thoracic and mediastinal disorders			23 (32.4%)	7 (18.4%)	30 (27.5%)				
		Mild	23 (32.4%)	7 (18.4%)	30 (27.5%)	2.1227 [0.8106, 5.5583]	1.7510 [0.8300, 3.6941] 0.1238	0.1385 [-0.0253, 0.3022]	0.6549
		Moderate	0	0	0				0.9766
		Severe	0	0	0				
	Cough		20 (28.2%)	2 (5.3%)	22 (20.2%)				
		Mild	20 (28.2%)	2 (5.3%)	22 (20.2%)	7.1647 [1.5631, 32.8415]	5.3187 [1.3178, 21.4670] 0.0048	0.2278 [0.1020, 0.3537]	0.0492
		Moderate	0	0	0				0.9766
		Severe	0	0	0				
	Rhinitis allergic		2 (2.8%)	2 (5.3%)	4 (3.7%)				
		Mild	2 (2.8%)	2 (5.3%)	4 (3.7%)	0.5046 [0.0661, 3.8534]	0.5231 [0.0768, 3.5621] 0.5042	-0.0252 [-0.1053, 0.0550]	0.9734
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 24 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		2 (2.8%)	2 (5.3%)	4 (3.7%)				
		Mild	2 (2.8%)	2 (5.3%)	4 (3.7%)	0.5174 [0.0698, 3.8381]	0.5319 [0.0782, 3.6173] 0.5167	-0.0247 [-0.1054, 0.0560]	0.9564
		Moderate	0	0	0				
		Severe	0	0	0				
	Asthma		2 (2.8%)	0	2 (1.8%)				
		Mild	2 (2.8%)	0	2 (1.8%)	1.6656 [0.1672, 16.5962]	1.6364 [0.1763, 15.1865] 0.3023	0.0281 [-0.0104, 0.0665]	0.9564
		Moderate	0	0	0				
		Severe	0	0	0				
	Adenoidal hypertrophy		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 25 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Allergic cough		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal congestion		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Oropharyngeal pain		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 26 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Nasal obstruction		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				
	Productive cough		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 27 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions			14 (19.7%)	10 (26.3%)	24 (22.0%)				
		Mild	13 (18.3%)	10 (26.3%)	23 (21.1%)	0.6303 [0.2464, 1.6120]	0.6977 [0.3374, 1.4429] 0.3367	-0.0793 [-0.2457, 0.0871]	0.4526
		Moderate	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9681
		Severe	0	0	0				
	Pyrexia		11 (15.5%)	6 (15.8%)	17 (15.6%)				
		Mild	11 (15.5%)	6 (15.8%)	17 (15.6%)	0.9791 [0.3313, 2.8939]	0.9824 [0.3941, 2.4490] 0.9698	-0.0028 [-0.1460, 0.1404]	0.5209
		Moderate	0	0	0				0.9987
		Severe	0	0	0				
	Injection site pain		3 (4.2%)	0	3 (2.8%)				
		Mild	3 (4.2%)	0	3 (2.8%)	2.2116 [0.2357, 20.7512]	2.1398 [0.2449, 18.6924] 0.2023	0.0423 [-0.0045, 0.0892]	0.9773
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 28 of 106

Table 1.22 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

			TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity				OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site pruritus		2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0749 [0.0943, 12.2577]	1.0732 [0.0985, 11.6866] 0.9540	0.0019 [-0.0619, 0.0657]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site bruising		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site erythema		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9590
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 29 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
General disorders and administration site conditions	Injection site reaction		1 (1.4%)	0	1 (0.9%)				
		Mild	0	0	0				0.9724
		Moderate	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Severe	0	0	0				
	Injection site swelling		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Pain		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 30 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
General disorders and administration site conditions	Peripheral swelling		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Injection site haemorrhage		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
Gastrointestinal disorders			14 (19.7%)	9 (23.7%)	23 (21.1%)				
		Mild	14 (19.7%)	9 (23.7%)	23 (21.1%)	0.7981 [0.3112, 2.0468]	0.8360 [0.3981, 1.7555] 0.6375	-0.0389 [-0.2041, 0.1263]	0.5939
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Gastrointestinal disorders	Diarrhoea		5 (7.0%)	3 (7.9%)	8 (7.3%)				
		Mild	5 (7.0%)	3 (7.9%)	8 (7.3%)	0.8838 [0.1993, 3.9187]	0.8920 [0.2250, 3.5360] 0.8720	-0.0085 [-0.1129, 0.0958]	0.3663
		Moderate	0	0	0				
		Severe	0	0	0				
	Dyspepsia		2 (2.8%)	2 (5.3%)	4 (3.7%)				
		Mild	2 (2.8%)	2 (5.3%)	4 (3.7%)	0.5301 [0.0725, 3.8741]	0.5407 [0.0796, 3.6725] 0.5249	-0.0242 [-0.1055, 0.0570]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal pain upper		2 (2.8%)	0	2 (1.8%)				
		Mild	2 (2.8%)	0	2 (1.8%)	2.8824 [0.1329, 62.5149]	2.7778 [0.1387, 55.6118] 0.2926	0.0285 [-0.0102, 0.0672]	0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Enteritis		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5000 [0.0289, 8.6494]	0.5185 [0.0350, 7.6815] 0.6321	-0.0128 [-0.0699, 0.0443]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 32 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Gastrointestinal disorders	Toothache		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5349 [0.0320, 8.9528]	0.5455 [0.0357, 8.3368] 0.6610	-0.0119 [-0.0693, 0.0456]	0.9988
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal distension		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Abdominal pain		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9590
		Moderate	0	0	0				
		Severe	0	0	0				
	Constipation		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 33 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Gastrointestinal disorders	Gastrointestinal disorder		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Noninfective gingivitis		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Nausea		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				
	Vomiting		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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. Daily rhGH [a] | | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders			9 (12.7%)	3 (7.9%)	12 (11.0%)				
		Mild	8 (11.3%)	3 (7.9%)	11 (10.1%)	1.4909 [0.3713, 5.9863]	1.4342 [0.4050, 5.0793] 0.5742	0.0343 [-0.0787, 0.1472]	0.5014
		Moderate	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Severe	0	0	0				
	Refraction disorder		2 (2.8%)	2 (5.3%)	4 (3.7%)				
		Mild	2 (2.8%)	2 (5.3%)	4 (3.7%)	0.5301 [0.0725, 3.8741]	0.5407 [0.0796, 3.6725] 0.5249	-0.0242 [-0.1055, 0.0570]	0.9734
		Moderate	0	0	0				
		Severe	0	0	0				
	Papilloedema		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5349 [0.0320, 8.9528]	0.5455 [0.0357, 8.3368] 0.6610	-0.0119 [-0.0693, 0.0456]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 35 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders	Conjunctivitis allergic		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Corneal epithelium defect		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye pain		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Eye swelling		1 (1.4%)	0	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 36 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Eye disorders	Eye swelling	Moderate	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Severe	0	0	0				
	Myopia		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Vitreous opacities		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Xerophthalmia		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Eye disorders	Vernal keratoconjunctivitis		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
Metabolism and nutrition disorders			6 (8.5%)	6 (15.8%)	12 (11.0%)				
		Mild	6 (8.5%)	6 (15.8%)	12 (11.0%)	0.4895 [0.1439, 1.6648]	0.5409 [0.1898, 1.5415] 0.2500	-0.0722 [-0.2035, 0.0591]	0.2523
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypertriglyceridaemia		4 (5.6%)	2 (5.3%)	6 (5.5%)				
		Mild	4 (5.6%)	2 (5.3%)	6 (5.5%)	1.1000 [0.1864, 6.4924]	1.0909 [0.2153, 5.5283] 0.9168	0.0048 [-0.0827, 0.0922]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 38 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders	Hypercholeste rolaemia		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5359 [0.0343, 8.3837]	0.5359 [0.0347, 8.2752] 0.6499	-0.0123 [-0.0710, 0.0463]	0.9580
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperuricaemi a		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5359 [0.0343, 8.3837]	0.5359 [0.0347, 8.2752] 0.6499	-0.0123 [-0.0710, 0.0463]	0.9785
		Moderate	0	0	0				
		Severe	0	0	0				
	Calcium deficiency		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Metabolism and nutrition disorders	Decreased appetite		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9681
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperglycaemia		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Hyperlipidaemia		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 40 of 106

Table 1.22 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=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	
Skin and subcutaneous tissue disorders			9 (12.7%)	2 (5.3%)	11 (10.1%)				
		Mild	9 (12.7%)	2 (5.3%)	11 (10.1%)	2.5512 [0.5315, 12.2451]	2.4102 [0.5356, 10.8454] 0.2268	0.0737 [-0.0324, 0.1798]	0.9784
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis allergic		2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0749 [0.0943, 12.2577]	1.0732 [0.0985, 11.6866] 0.9540	0.0019 [-0.0619, 0.0657]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria		3 (4.2%)	0	3 (2.8%)				
		Mild	3 (4.2%)	0	3 (2.8%)	2.2161 [0.2357, 20.8370]	2.1445 [0.2460, 18.6975] 0.2046	0.0419 [-0.0047, 0.0885]	0.9773
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 41 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Eczema		2 (2.8%)	0	2 (1.8%)				
		Mild	2 (2.8%)	0	2 (1.8%)	1.6656 [0.1672, 16.5962]	1.6364 [0.1763, 15.1865] 0.3023	0.0281 [-0.0104, 0.0665]	0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Dermatitis contact		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 42 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Dyshidrotic eczema		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Rash		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Urticaria chronic		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 43 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Skin and subcutaneous tissue disorders	Urticaria papular		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
Injury, poisoning and procedural complications			5 (7.0%)	1 (2.6%)	6 (5.5%)				
		Mild	4 (5.6%)	1 (2.6%)	5 (4.6%)	2.1697 [0.2386, 19.7273]	2.1264 [0.2475, 18.2693] 0.4801	0.0300 [-0.0448, 0.1047]	0.4204
		Moderate	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Severe	0	0	0				
	Head injury		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5359 [0.0343, 8.3837]	0.5359 [0.0347, 8.2752] 0.6499	-0.0123 [-0.0710, 0.0463]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 44 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Injury, poisoning and procedural complications	Eye injury		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Joint injury		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Ligament sprain		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Skin laceration		1 (1.4%)	0	1 (0.9%)				
		Mild	0	0	0				0.9724

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 45 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Injury, poisoning and procedural complications	Skin laceration	Moderate	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780]	0.0138 [-0.0133, 0.0409]	0.9804
							0.4715		
		Severe	0	0	0				
	Animal scratch		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
Nervous system disorders			1 (1.4%)	5 (13.2%)	6 (5.5%)				
		Mild	1 (1.4%)	5 (13.2%)	6 (5.5%)	0.0884 [0.0097, 0.8087]	0.1091 [0.0135, 0.8808] 0.0105	-0.1165 [-0.2264, -0.0065]	0.3622
		Moderate	0	0	0				
		Severe	0	0	0				
	Headache		0	4 (10.5%)	4 (3.7%)				
		Mild	0	4 (10.5%)	4 (3.7%)	0.0512 [0.0026, 0.9959]	0.0617 [0.0035, 1.1002] 0.0056	-0.1046 [-0.2019, -0.0072]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 46 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Nervous system disorders	Dizziness		1 (1.4%)	1 (2.6%)	2 (1.8%)				
		Mild	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5349 [0.0320, 8.9528]	0.5455 [0.0357, 8.3368] 0.6610	-0.0119 [-0.0693, 0.0456]	0.9785
		Moderate	0	0	0				
		Severe	0	0	0				
Blood and lymphatic system disorders			4 (5.6%)	1 (2.6%)	5 (4.6%)				
		Mild	3 (4.2%)	1 (2.6%)	4 (3.7%)	1.6481 [0.1641, 16.5496]	1.6186 [0.1733, 15.1158] 0.6713	0.0162 [-0.0528, 0.0851]	0.7928
		Moderate	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Severe	0	0	0				
	Anaemia		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9984
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 47 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Blood and lymphatic system disorders	Granulocytopenia		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypochromic anaemia		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Lymphadenitis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Thymus disorder		1 (1.4%)	0	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 48 of 106

Table 1.22 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=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Blood and lymphatic system disorders	Thymus disorder	Moderate	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Severe	0	0	0				
Endocrine disorders			2 (2.8%)	1 (2.6%)	3 (2.8%)				
		Mild	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0952 [0.0942, 12.7391]	1.0909 [0.1042, 11.4201] 0.9425	0.0024 [-0.0609, 0.0657]	0.9998
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypothyroidism		2 (2.8%)	0	2 (1.8%)				
		Mild	2 (2.8%)	0	2 (1.8%)	2.8824 [0.1329, 62.5149]	2.7778 [0.1387, 55.6118] 0.2926	0.0285 [-0.0102, 0.0672]	0.9815
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 49 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Endocrine disorders	Precocious puberty		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
Musculoskeletal and connective tissue disorders			3 (4.2%)	0	3 (2.8%)				
		Mild	3 (4.2%)	0	3 (2.8%)	4.1325 [0.2047, 83.4175]	3.8889 [0.2092, 72.2910] 0.1940	0.0428 [-0.0043, 0.0898]	0.9990
		Moderate	0	0	0				
		Severe	0	0	0				
	Arthralgia		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 50 of 106

Table 1.22 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. Daily rhGH [a]			
System Organ Class	Preferred Term	Severity	TransCon hGH (N=71)	Daily rhGH (N=38)	Total (N=109)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Musculoskeletal and connective tissue disorders	Pain in extremity		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Scoliosis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
Reproductive system and breast disorders			3 (4.2%)	0	3 (2.8%)				
		Mild	3 (4.2%)	0	3 (2.8%)	2.2116 [0.2357, 20.7512]	2.1398 [0.2449, 18.6924] 0.2023	0.0423 [-0.0045, 0.0892]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 51 of 106

Anhang 4-H   Seite 588 von 682

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Reproductive system and breast disorders	Gynaecomastia		2 (2.8%)	0	2 (1.8%)				
		Mild	2 (2.8%)	0	2 (1.8%)	2.8824 [0.1329, 62.5149]	2.7778 [0.1387, 55.6118] 0.2926	0.0285 [-0.0102, 0.0672]	0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Balanoposthitis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6415 [0.0628, 42.9325]	1.6071 [0.0697, 37.0780] 0.4715	0.0138 [-0.0133, 0.0409]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Pelvic fluid collection		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 52 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Reproductive system and breast disorders	Testicular appendage torsion		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				
Congenital, familial and genetic disorders			2 (2.8%)	0	2 (1.8%)				
		Mild	2 (2.8%)	0	2 (1.8%)	2.8824 [0.1329, 62.5149]	2.7778 [0.1387, 55.6118] 0.2926	0.0285 [-0.0102, 0.0672]	0.9815
		Moderate	0	0	0				
		Severe	0	0	0				
	Buried penis syndrome		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 53 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Congenital, familial and genetic disorders	Supernumerary teeth		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
Cardiac disorders			1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9982
		Moderate	0	0	0				
		Severe	0	0	0				
	Wandering pacemaker		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	
Cardiac disorders	Myocarditis		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				
Immune system disorders			1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9590
		Moderate	0	0	0				
		Severe	0	0	0				
	Food allergy		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
	Hypersensitivity		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 55 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Renal and urinary disorders			0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
	Nocturia		0	1 (2.6%)	1 (0.9%)				
		Mild	0	1 (2.6%)	1 (0.9%)	0.1760 [0.0069, 4.4920]	0.1852 [0.0078, 4.3782] 0.1757	-0.0261 [-0.0769, 0.0246]	0.9738
		Moderate	0	0	0				
		Severe	0	0	0				
Vascular disorders			1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 56 of 106

Table 1.22 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]	Subgroup Interaction p-value
Vascular disorders	Cyanosis		1 (1.4%)	0	1 (0.9%)				
		Mild	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
		Moderate	0	0	0				
		Severe	0	0	0				
Ear and labyrinth disorders			0	0	0				
		Mild	0	0	0				0.9987
		Moderate	0	0	0				
		Severe	0	0	0				
	Cerumen impaction		0	0	0				
		Mild	0	0	0				0.9750
		Moderate	0	0	0				
		Severe	0	0	0				
	Motion sickness		0	0	0				
		Mild	0	0	0				0.9724
		Moderate	0	0	0				
		Severe	0	0	0				

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 57 of 106

Table 1.22 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Any adverse event			29 (100.0%)	14 (93.3%)	43 (97.7%)			
		Mild	27 (93.1%)	12 (80.0%)	39 (88.6%)	3.1190 [0.4841, 20.0944]	1.1633 [0.8802, 1.5375] 0.2061	0.1305 [-0.0972, 0.3582]
		Moderate	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2386 [0.0198, 2.8774]	0.2637 [0.0264, 2.6340] 0.2303	-0.0982 [-0.2833, 0.0868]
		Severe	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
Infections and infestations			15 (51.7%)	12 (80.0%)	27 (61.4%)			
		Mild	14 (48.3%)	11 (73.3%)	25 (56.8%)	0.3123 [0.0746, 1.3078]	0.6633 [0.4174, 1.0542] 0.1126	-0.2463 [-0.5228, 0.0301]
		Moderate	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Severe	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Upper respiratory tract infection		12 (41.4%)	10 (66.7%)	22 (50.0%)			
		Mild	12 (41.4%)	9 (60.0%)	21 (47.7%)	0.4541 [0.1210, 1.7048]	0.6953 [0.3890, 1.2429] 0.2449	-0.1818 [-0.4780, 0.1144]
		Moderate	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Severe	0	0	0			
	Tonsillitis		2 (6.9%)	2 (13.3%)	4 (9.1%)			
		Mild	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.4941 [0.0625, 3.9078]	0.5275 [0.0831, 3.3486] 0.4968	-0.0630 [-0.2593, 0.1332]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasopharyngitis		1 (3.4%)	2 (13.3%)	3 (6.8%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5000 [0.0271, 9.2384]	0.5333 [0.0382, 7.4413] 0.6437	-0.0308 [-0.1704, 0.1088]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 59 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Nasopharyngitis	Moderate	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Severe	0	0	0			
	Respiratory tract infection		1 (3.4%)	2 (13.3%)	3 (6.8%)			
		Mild	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2386 [0.0198, 2.8774]	0.2637 [0.0264, 2.6340] 0.2303	-0.0982 [-0.2833, 0.0868]
		Moderate	0	0	0			
		Severe	0	0	0			
	Bronchitis		2 (6.9%)	0	2 (4.5%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
	Gastroenteritis		0	2 (13.3%)	2 (4.5%)			
		Mild	0	2 (13.3%)	2 (4.5%)	0.1553 [0.0148, 1.6293]	0.1826 [0.0205, 1.6219] 0.0491	-0.1334 [-0.3055, 0.0387]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 60 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Conjunctivitis		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Gastrointestinal bacterial infection		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hand-foot-and-mouth disease		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 61 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Mumps		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Myringitis		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis media acute		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Periodontitis		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 62 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Peritonsillar abscess		0	1 (6.7%)	1 (2.3%)			
		Mild	0	0	0			
		Moderate	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Severe	0	0	0			
	Pharyngitis		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pneumonia		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1494 [0.0053, 4.1815]	0.1778 [0.0081, 3.8815] 0.1573	-0.0674 [-0.1943, 0.0594]
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinusitis		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Abscess limb		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Bacterial infection		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Chronic sinusitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Chronic tonsillitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Folliculitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 64 of 106

Table 1.22 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. Daily rhGH [a] | | |
| | | | | | | | RR | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	OR [95 %-CI] [b]	[95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Gastroenteritis viral		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpangina		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Herpes virus 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			
	Infectious mononucleosis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 65 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Infections and infestations	Influenza		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Laryngitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Oral herpes		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Otitis media		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	Rhinitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Sinobronchitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Subcutaneous abscess		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tonsillitis bacterial		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tracheitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 67 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Infections and infestations	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			
Investigations			16 (55.2%)	7 (46.7%)	23 (52.3%)			
		Mild	16 (55.2%)	7 (46.7%)	23 (52.3%)	1.3973 [0.4049, 4.8222]	1.1818 [0.6257, 2.2322] 0.6010	0.0850 [-0.2287, 0.3988]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood glucose increased		6 (20.7%)	5 (33.3%)	11 (25.0%)			
		Mild	6 (20.7%)	5 (33.3%)	11 (25.0%)	0.4385 [0.0919, 2.0915]	0.6070 [0.2431, 1.5158] 0.3074	-0.1320 [-0.3887, 0.1248]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Insulin-like growth factor increased		8 (27.6%)	0	8 (18.2%)			
		Mild	8 (27.6%)	0	8 (18.2%)	6.4245 [0.7344, 56.2043]	4.8317 [0.6642, 35.1500] 0.0267	0.2771 [0.1143, 0.4399]
		Moderate	0	0	0			
		Severe	0	0	0			
	Low density lipoprotein increased		2 (6.9%)	2 (13.3%)	4 (9.1%)			
		Mild	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.5217 [0.0749, 3.6363]	0.5217 [0.0758, 3.5897] 0.4905	-0.0645 [-0.2700, 0.1410]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood alkaline phosphatase increased		2 (6.9%)	1 (6.7%)	3 (6.8%)			
		Mild	2 (6.9%)	1 (6.7%)	3 (6.8%)	1.0769 [0.0824, 14.0752]	1.0667 [0.1133, 10.0381] 0.9559	0.0044 [-0.1467, 0.1555]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 69 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Electrocardiogram T wave peaked		2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	1.7122 [0.1641, 17.8685]	1.6430 [0.1849, 14.5969] 0.3094	0.0689 [-0.0233, 0.1611]
		Moderate	0	0	0			
		Severe	0	0	0			
	Alanine aminotransferase increased		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Basophil count increased		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Investigations	Blood glucose abnormal		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood iron increased		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood lactate dehydrogenase increased		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood phosphorus increased		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood potassium increased		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood pressure increased		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 72 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood thyroid stimulating hormone increased		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood urea increased		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1494 [0.0053, 4.1815]	0.1778 [0.0081, 3.8815] 0.1573	-0.0674 [-0.1943, 0.0594]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cortisol decreased		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1494 [0.0053, 4.1815]	0.1778 [0.0081, 3.8815] 0.1573	-0.0674 [-0.1943, 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 73 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Electrocardiogram high voltage		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eosinophil count increased		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Aspartate 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Blood cholesterol increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood triglycerides increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Blood uric acid increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Electrocardiogram ST segment abnormal		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 75 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Haemoglobin decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hepatic enzyme increased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Lipids 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 76 of 106

Table 1.22 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	Liver function test abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroid function test abnormal		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thyroxine free decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Tri-iodothyronine free 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 77 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Investigations	White blood cell count decreased		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Respiratory, thoracic and mediastinal disorders			10 (34.5%)	6 (40.0%)	16 (36.4%)			
		Mild	10 (34.5%)	4 (26.7%)	14 (31.8%)	1.4078 [0.3777, 5.2469]	1.2951 [0.4721, 3.5529] 0.6008	0.0792 [-0.2171, 0.3754]
		Moderate	0	2 (13.3%)	2 (4.5%)	0.1553 [0.0148, 1.6293]	0.1826 [0.0205, 1.6219] 0.0491	-0.1334 [-0.3055, 0.0387]
		Severe	0	0	0			
	Cough		7 (24.1%)	6 (40.0%)	13 (29.5%)			
		Mild	7 (24.1%)	4 (26.7%)	11 (25.0%)	0.8854 [0.2246, 3.4894]	0.9071 [0.3053, 2.6947] 0.8596	-0.0249 [-0.3083, 0.2584]
		Moderate	0	2 (13.3%)	2 (4.5%)	0.1553 [0.0148, 1.6293]	0.1826 [0.0205, 1.6219] 0.0491	-0.1334 [-0.3055, 0.0387]
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 78 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea		2 (6.9%)	2 (13.3%)	4 (9.1%)			
		Mild	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.5217 [0.0749, 3.6363]	0.5217 [0.0758, 3.5897] 0.4905	-0.0645 [-0.2700, 0.1410]
		Moderate	0	0	0			
		Severe	0	0	0			
	Asthma		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nasal obstruction		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 79 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Productive cough		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Rhinitis allergic		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Adenoidal hypertrophy		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Allergic cough		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:13 Page 80 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Respiratory, thoracic and mediastinal disorders	Nasal congestion		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Oropharyngeal pain		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			
General disorders and administration site conditions			6 (20.7%)	3 (20.0%)	9 (20.5%)			
		Mild	5 (17.2%)	2 (13.3%)	7 (15.9%)	1.3580 [0.2312, 7.9747]	1.2967 [0.2849, 5.9019] 0.7394	0.0396 [-0.1810, 0.2602]

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
General disorders and administration site conditions		Moderate	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5000 [0.0271, 9.2384]	0.5333 [0.0382, 7.4413] 0.6437	-0.0308 [-0.1704, 0.1088]
		Severe	0	0	0			
	Pyrexia		5 (17.2%)	2 (13.3%)	7 (15.9%)			
		Mild	4 (13.8%)	1 (6.7%)	5 (11.4%)	2.2174 [0.2237, 21.9822]	2.0435 [0.2547, 16.3944] 0.4937	0.0704 [-0.1078, 0.2485]
		Moderate	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5000 [0.0271, 9.2384]	0.5333 [0.0382, 7.4413] 0.6437	-0.0308 [-0.1704, 0.1088]
		Severe	0	0	0			
	Injection site erythema		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 82 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
General disorders and administratio n site conditions	Injection site haemorrhage		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site reaction		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site bruising		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 83 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
General disorders and administration site conditions	Injection site pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site pruritus		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Injection site swelling		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Peripheral 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 84 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders			6 (20.7%)	2 (13.3%)	8 (18.2%)			
		Mild	6 (20.7%)	2 (13.3%)	8 (18.2%)	1.5652 [0.3282, 7.4653]	1.5652 [0.3228, 7.5898] 0.5348	0.0762 [-0.1748, 0.3273]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypercholesterolaemia		2 (6.9%)	2 (13.3%)	4 (9.1%)			
		Mild	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.5217 [0.0749, 3.6363]	0.5217 [0.0758, 3.5897] 0.4905	-0.0645 [-0.2700, 0.1410]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypertriglyceridaemia		3 (10.3%)	0	3 (6.8%)			
		Mild	3 (10.3%)	0	3 (6.8%)	4.7600 [0.2169, 104.4693]	3.9375 [0.2281, 67.9639] 0.1846	0.1056 [-0.0062, 0.2173]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 85 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Decreased appetite		1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5217 [0.0334, 8.1431]	0.5217 [0.0341, 7.9799] 0.6342	-0.0323 [-0.1790, 0.1145]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperuricaemia		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Calcium deficiency		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Hyperglycaemia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 86 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Metabolism and nutrition disorders	Hyperlipidaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Gastrointestinal disorders			3 (10.3%)	3 (20.0%)	6 (13.6%)			
		Mild	3 (10.3%)	3 (20.0%)	6 (13.6%)	0.4615 [0.0799, 2.6645]	0.5221 [0.1209, 2.2551] 0.3910	-0.0953 [-0.3247, 0.1341]
		Moderate	0	0	0			
		Severe	0	0	0			
	Diarrhoea		1 (3.4%)	2 (13.3%)	3 (6.8%)			
		Mild	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2386 [0.0198, 2.8774]	0.2637 [0.0264, 2.6340] 0.2303	-0.0982 [-0.2833, 0.0868]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal pain		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Gastrointestinal disorder		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Nausea		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Vomiting		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Abdominal distension		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Gastrointestinal disorders	Abdominal pain upper		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			
	Dyspepsia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Enteritis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Noninfective gingivitis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 89 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders			2 (6.9%)	1 (6.7%)	3 (6.8%)			
		Mild	2 (6.9%)	1 (6.7%)	3 (6.8%)	1.0769 [0.0824, 14.0752]	1.0667 [0.1133, 10.0381] 0.9559	0.0044 [-0.1467, 0.1555]
		Moderate	0	0	0			
		Severe	0	0	0			
	Anaemia		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Granulocytopenia		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Lymphadenitis		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 90 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Blood and lymphatic system disorders	Hypochromic anaemia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Thymus disorder		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Ear and labyrinth disorders			1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5000 [0.0271, 9.2384]	0.5333 [0.0382, 7.4413] 0.6437	-0.0308 [-0.1704, 0.1088]
		Moderate	0	0	0			
		Severe	0	0	0			
	Cerumen impaction		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 91 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Ear and labyrinth disorders	Motion sickness		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
Eye disorders			1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5111 [0.0312, 8.3762]	0.5111 [0.0306, 8.5489] 0.6342	-0.0323 [-0.1771, 0.1126]
		Moderate	0	0	0			
		Severe	0	0	0			
	Refraction disorder		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 92 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Vernal keratoconjunctivitis		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		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			
	Corneal epithelium defect		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 93 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Eye disorders	Eye swelling		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Myopia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Papilloedema		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Vitreous opacities		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Xerophthalmia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications			1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5111 [0.0312, 8.3762]	0.5111 [0.0306, 8.5489] 0.6342	-0.0323 [-0.1771, 0.1126]
		Moderate	0	0	0			
		Severe	0	0	0			
	Animal scratch		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Skin laceration		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Eye 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 95 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Injury, poisoning and procedural complications	Head injury		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Joint 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			
Musculoskeletal and connective tissue disorders			2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	1.7122 [0.1641, 17.8685]	1.6430 [0.1849, 14.5969] 0.3094	0.0689 [-0.0233, 0.1611]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 96 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Musculoskeletal and connective tissue disorders	Arthralgia		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pain in extremity		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Scoliosis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 97 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Nervous system disorders			1 (3.4%)	1 (6.7%)	2 (4.5%)			
		Mild	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.5111 [0.0312, 8.3762]	0.5111 [0.0306, 8.5489] 0.6342	-0.0323 [-0.1771, 0.1126]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dizziness		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Headache		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Reproductive system and breast disorders			2 (6.9%)	0	2 (4.5%)			
		Mild	2 (6.9%)	0	2 (4.5%)	1.7122 [0.1641, 17.8685]	1.6430 [0.1849, 14.5969] 0.3094	0.0689 [-0.0233, 0.1611]
		Moderate	0	0	0			
		Severe	0	0	0			
	Pelvic fluid collection		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Testicular appendage torsion		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:13 Page 99 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Reproductive system and breast disorders	Balanoposthitis		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Gynaecomastia		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Cardiac disorders			1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			
	Myocarditis		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]
		Moderate	0	0	0			
		Severe	0	0	0			

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

Source: ...\biometrics\hgh\ct-301-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 100 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Cardiac disorders	Wandering pacemaker		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Immune system disorders			0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Hypersensitivity		0	1 (6.7%)	1 (2.3%)			
		Mild	0	1 (6.7%)	1 (2.3%)	0.1613 [0.0058, 4.4489]	0.1875 [0.0085, 4.1400] 0.1709	-0.0660 [-0.1917, 0.0597]
		Moderate	0	0	0			
		Severe	0	0	0			
	Food allergy		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 101 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders			1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Urticaria papular		1 (3.4%)	0	1 (2.3%)			
		Mild	1 (3.4%)	0	1 (2.3%)	1.6667 [0.0601, 46.2273]	1.6000 [0.0733, 34.9335] 0.4795	0.0337 [-0.0320, 0.0995]
		Moderate	0	0	0			
		Severe	0	0	0			
	Dermatitis		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			

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

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Skin and subcutaneous tissue disorders	Dermatitis contact		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Dyshidrotic eczema		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			
	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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 103 of 106

Table 1.22 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. Daily rhGH [a] | | |
| | | | TransCon hGH (N=29) | Daily rhGH (N=15) | Total (N=44) | OR [95 %-CI] [b] | RR [95 %-CI] [b] p-value [c] | RD [95 %-CI] [b] |
System Organ Class	Preferred Term	Severity						
Skin and subcutaneous tissue disorders	Urticaria chronic		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
Congenital, familial and genetic disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Buried penis syndrome		0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Supernumerary teeth		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 104 of 106

Table 1.22 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]		
						OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value [c]	RD [95 %-CI] [b]
Endocrine disorders			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			
	Precocious puberty		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			
	Nocturia		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022

Table 1.22 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. Daily rhGH [a] | | |
System Organ Class	Preferred Term	Severity	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	OR [95 %-CI] [b]	RR [95 %-CI] [b] p-value[c]	RD [95 %-CI] [b]
Vascular disorders			0	0	0			
		Mild	0	0	0			
		Moderate	0	0	0			
		Severe	0	0	0			
	Cyanosis		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-cn-visen\adhoc\amnog_dossier\prog\t-teae-maxsev-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:13 Page 106 of 106

Table 1.30 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=42)	Daily rhGH (N=22)	Total (N=64)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	2 (4.8%)	4 (18.2%)	6 (9.4%)	0.2250 [0.0377, 1.3425]	0.2619 [0.0520, 1.3196] 0.0826	-0.1342 [-0.3078, 0.0394]	0.0794
	MILD	2 (4.8%)	4 (18.2%)	6 (9.4%)	0.2250 [0.0377, 1.3425]	0.2619 [0.0520, 1.3196] 0.0826	-0.1342 [-0.3078, 0.0394]	0.1168
	MODERATE	0	0	0				0.9776
	SEVERE	0	0	0				
Bruising	ANY	3 (7.1%)	1 (4.5%)	4 (6.3%)	1.6154 [0.1580, 16.5120]	1.5714 [0.1735, 14.2334] 0.6858	0.0260 [-0.0908, 0.1428]	0.5464
	MILD	3 (7.1%)	0	3 (4.7%)	3.9873 [0.1969, 80.7365]	3.7442 [0.2020, 69.3949] 0.2027	0.0714 [-0.0065, 0.1493]	0.9657
	MODERATE	0	1 (4.5%)	1 (1.6%)	0.1686 [0.0066, 4.3159]	0.1783 [0.0076, 4.2038] 0.1671	-0.0455 [-0.1325, 0.0416]	0.9756
	SEVERE	0	0	0				
Swelling	ANY	4 (9.5%)	4 (18.2%)	8 (12.5%)	0.4737 [0.1062, 2.1125]	0.5238 [0.1447, 1.8959] 0.3237	-0.0866 [-0.2706, 0.0974]	0.9482

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 1 of 4

Table 1.30 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

| | | TransCon hGH (N=42) | Daily rhGH (N=22) | Total (N=64) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
| | | | | | OR [95%-CI] [b] | RR [95%-CI] [b] P-value [c] | RD [95%-CI] [b] | |
Symptom	Severity							
Swelling	MILD	4 (9.5%)	4 (18.2%)	8 (12.5%)	0.4737 [0.1062, 2.1125]	0.5238 [0.1447, 1.8959] 0.3237	-0.0866 [-0.2706, 0.0974]	0.9482
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	1 (2.4%)	3 (13.6%)	4 (6.3%)				0.5099
Overall number of abnormal injection-site reactions		6 (14.3%)	7 (31.8%)	13 (20.3%)	0.3571 [0.1028, 1.2412]	0.4490 [0.1718, 1.1734] 0.1004	-0.1753 [-0.3969, 0.0462]	0.4050

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 2 of 4

Table 1.30 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	5 (8.6%)	1 (3.2%)	6 (6.7%)	2.8302 [0.3157, 25.3703]	2.6724 [0.3265, 21.8733] 0.3362	0.0539 [-0.0414, 0.1493]	
	MILD	4 (6.9%)	1 (3.2%)	5 (5.6%)	2.2222 [0.2375, 20.7969]	2.1379 [0.2497, 18.3077] 0.4762	0.0367 [-0.0534, 0.1268]	
	MODERATE	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]	
	SEVERE	0	0	0				
Bruising	ANY	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]	
	MILD	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 3 of 4

Table 1.30 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Swelling	MILD	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	1 (1.7%)	1 (3.2%)	2 (2.2%)				
Overall number of abnormal injection-site reactions		6 (10.3%)	4 (12.9%)	10 (11.2%)	0.7788 [0.2023, 2.9980]	0.8017 [0.2445, 2.6291] 0.7173	-0.0256 [-0.1672, 0.1161]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:17 Page 4 of 4

Table 1.31 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	6 (6.9%)	4 (8.9%)	10 (7.6%)	0.7614 [0.2054, 2.8222]	0.7755 [0.2293, 2.6227] 0.6830	-0.0200 [-0.1194, 0.0794]	0.8721
	MILD	5 (5.7%)	4 (8.9%)	9 (6.8%)	0.6256 [0.1603, 2.4411]	0.6458 [0.1821, 2.2901] 0.4982	-0.0315 [-0.1283, 0.0652]	0.9666
	MODERATE	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
	SEVERE	0	0	0				
Bruising	ANY	4 (4.6%)	2 (4.4%)	6 (4.5%)	1.0326 [0.1812, 5.8844]	1.0310 [0.1965, 5.4095] 0.9713	0.0014 [-0.0731, 0.0758]	0.9999
	MILD	4 (4.6%)	1 (2.2%)	5 (3.8%)	2.0902 [0.2313, 18.8855]	2.0674 [0.2330, 18.3445] 0.5020	0.0237 [-0.0384, 0.0857]	0.9984
	MODERATE	0	1 (2.2%)	1 (0.8%)	0.1646 [0.0064, 4.2281]	0.1750 [0.0074, 4.1114] 0.1626	-0.0223 [-0.0654, 0.0208]	0.9754
	SEVERE	0	0	0				
Swelling	ANY	5 (5.7%)	4 (8.9%)	9 (6.8%)	0.6015 [0.1470, 2.4606]	0.6423 [0.1892, 2.1808] 0.4811	-0.0319 [-0.1256, 0.0619]	0.9779

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

Table 1.31 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

		TransCon hGH (N=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
Symptom	Severity				OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Swelling	MILD	5 (5.7%)	4 (8.9%)	9 (6.8%)	0.6015 [0.1470, 2.4606]	0.6423 [0.1892, 2.1808] 0.4811	-0.0319 [-0.1256, 0.0619]	0.9779
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	2 (2.3%)	4 (8.9%)	6 (4.5%)				
Overall number of abnormal injection-site reactions		11 (12.6%)	9 (20.0%)	20 (15.2%)	0.5720 [0.2161, 1.5141]	0.6308 [0.2844, 1.3991] 0.2610	-0.0739 [-0.2090, 0.0612]	0.5520

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 2 of 4

Table 1.31 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=13) | Daily rhGH (N=8) | Total (N=21) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	1 (7.7%)	1 (12.5%)	2 (9.5%)	0.6250 [0.0395, 9.8915]	0.6250 [0.0363, 10.7605] 0.7439	-0.0455 [-0.3266, 0.2357]	
	MILD	1 (7.7%)	1 (12.5%)	2 (9.5%)	0.6250 [0.0395, 9.8915]	0.6250 [0.0363, 10.7605] 0.7439	-0.0455 [-0.3266, 0.2357]	
	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	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]	
	MILD	0	1 (12.5%)	1 (4.8%)	0.1746 [0.0060, 5.0406]	0.2121 [0.0100, 4.5109] 0.1967	-0.1263 [-0.3563, 0.1038]	
	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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 3 of 4

Table 1.31 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=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Overall number of abnormal injection-site reactions		1 (7.7%)	2 (25.0%)	3 (14.3%)	0.2688 [0.0220, 3.2874]	0.3061 [0.0299, 3.1296]	-0.1717 [-0.5109, 0.1675]	
						0.3018		

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:17 Page 4 of 4

Table 1.32 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	1 (4.0%)	3 (23.1%)	4 (10.5%)	0.1579 [0.0170, 1.4658]	0.1742 [0.0195, 1.5561] 0.0731	-0.1919 [-0.4385, 0.0547]	0.0937
	MILD	1 (4.0%)	3 (23.1%)	4 (10.5%)	0.1579 [0.0170, 1.4658]	0.1742 [0.0195, 1.5561] 0.0731	-0.1919 [-0.4385, 0.0547]	0.1257
	MODERATE	0	0	0				0.9815
	SEVERE	0	0	0				
Bruising	ANY	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9738
	MILD	0	1 (7.7%)	1 (2.6%)	0.1619 [0.0059, 4.4065]	0.1852 [0.0083, 4.1349] 0.1693	-0.0765 [-0.2210, 0.0680]	0.9462
	MODERATE	0	0	0				0.9751
	SEVERE	0	0	0				
Swelling	ANY	0	3 (23.1%)	3 (7.9%)	0.0982 [0.0094, 1.0318]	0.1401 [0.0173, 1.1362] 0.0123	-0.2324 [-0.4617, -0.0030]	0.9656

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

Table 1.32 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=25) | Daily rhGH (N=13) | Total (N=38) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Swelling	MILD	0	3 (23.1%)	3 (7.9%)	0.0982 [0.0094, 1.0318]	0.1401 [0.0173, 1.1362]	-0.2324 [-0.4617, -0.0030]	0.9656
						0.0123		
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	0	1 (7.7%)	1 (2.6%)				
Overall number of abnormal injection-site reactions		1 (4.0%)	6 (46.2%)	7 (18.4%)	0.0507 [0.0052, 0.4929]	0.0877 [0.0119, 0.6473]	-0.4213 [-0.7037, -0.1389]	0.0135
						0.0020		

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 2 of 4

Table 1.32 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=75) | Daily rhGH (N=40) | Total (N=115) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	6 (8.0%)	2 (5.0%)	8 (7.0%)	1.6349 [0.3187, 8.3873]	1.5976 [0.3347, 7.6257] 0.5509	0.0300 [-0.0623, 0.1222]	
	MILD	5 (6.7%)	2 (5.0%)	7 (6.1%)	1.3512 [0.2515, 7.2607]	1.3305 [0.2695, 6.5690] 0.7252	0.0166 [-0.0719, 0.1050]	
	MODERATE	1 (1.3%)	0	1 (0.9%)	1.6667 [0.0652, 42.6342]	1.6429 [0.0697, 38.7219] 0.4639	0.0134 [-0.0126, 0.0394]	
	SEVERE	0	0	0				
Bruising	ANY	4 (5.3%)	1 (2.5%)	5 (4.3%)	2.2309 [0.2339, 21.2743]	2.1223 [0.2514, 17.9179] 0.4800	0.0281 [-0.0411, 0.0974]	
	MILD	4 (5.3%)	0	4 (3.5%)	2.7033 [0.2968, 24.6189]	2.5862 [0.3041, 21.9950] 0.1390	0.0532 [0.0024, 0.1040]	
	MODERATE	0	1 (2.5%)	1 (0.9%)	0.1691 [0.0065, 4.3689]	0.1810 [0.0077, 4.2291] 0.1693	-0.0251 [-0.0735, 0.0234]	
	SEVERE	0	0	0				
Swelling	ANY	5 (6.7%)	2 (5.0%)	7 (6.1%)	1.3693 [0.2433, 7.7081]	1.3259 [0.2794, 6.2926] 0.7236	0.0163 [-0.0695, 0.1022]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 3 of 4

Table 1.32 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Swelling	MILD	5 (6.7%)	2 (5.0%)	7 (6.1%)	1.3693 [0.2433, 7.7081]	1.3259 [0.2794, 6.2926] 0.7236	0.0163 [-0.0695, 0.1022]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	2 (2.7%)	3 (7.5%)	5 (4.3%)				
Overall number of abnormal injection-site reactions		11 (14.7%)	5 (12.5%)	16 (13.9%)	1.2057 [0.3799, 3.8264]	1.1694 [0.4441, 3.0788] 0.7518	0.0212 [-0.1068, 0.1492]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 4 of 4

Table 1.33 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	7 (8.4%)	5 (10.6%)	12 (9.2%)	0.7761 [0.2369, 2.5423]	0.7906 [0.2652, 2.3567] 0.6720	-0.0225 [-0.1308, 0.0858]	1.0000
	MILD	6 (7.2%)	5 (10.6%)	11 (8.5%)	0.6551 [0.1920, 2.2357]	0.6760 [0.2185, 2.0913] 0.4948	-0.0349 [-0.1404, 0.0707]	1.0000
	MODERATE	1 (1.2%)	0	1 (0.8%)	1.8132 [0.0713, 46.0863]	1.7872 [0.0754, 42.3891] 0.4436	0.0123 [-0.0114, 0.0361]	0.9997
	SEVERE	0	0	0				
Bruising	ANY	4 (4.8%)	1 (2.1%)	5 (3.8%)	2.2965 [0.2434, 21.6703]	2.1914 [0.2602, 18.4575] 0.4599	0.0258 [-0.0353, 0.0869]	1.0000
	MILD	4 (4.8%)	0	4 (3.1%)	2.8284 [0.3118, 25.6553]	2.7145 [0.3179, 23.1757] 0.1320	0.0474 [0.0017, 0.0932]	0.9987
	MODERATE	0	1 (2.1%)	1 (0.8%)	0.1733 [0.0067, 4.4572]	0.1842 [0.0078, 4.3243] 0.1738	-0.0216 [-0.0632, 0.0200]	0.9996
	SEVERE	0	0	0				
Swelling	ANY	4 (4.8%)	5 (10.6%)	9 (6.9%)	0.3991 [0.0992, 1.6065]	0.4409 [0.1276, 1.5230] 0.1886	-0.0601 [-0.1583, 0.0380]	0.9980

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 1 of 4

Table 1.33 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

| | | TransCon hGH (N=83) | Daily rhGH (N=47) | Total (N=130) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
| | | | | | OR [95%-CI] [b] | RR [95%-CI] [b] P-value [c] | RD [95%-CI] [b] | |
Symptom	Severity							
Swelling	MILD	4 (4.8%)	5 (10.6%)	9 (6.9%)	0.3991 [0.0992, 1.6065]	0.4409 [0.1276, 1.5230] 0.1886	-0.0601 [-0.1583, 0.0380]	0.9980
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	1 (1.2%)	4 (8.5%)	5 (3.8%)				
Overall number of abnormal injection-site reactions		11 (13.3%)	10 (21.3%)	21 (16.2%)	0.5585 [0.2180, 1.4311]	0.6176 [0.2853, 1.3369] 0.2220	-0.0820 [-0.2201, 0.0560]	0.9960

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

Table 1.33 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=14)	Daily rhGH (N=5)	Total (N=19)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	0	0	0				
	MILD	0	0	0				
	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 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]	
	MILD	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	1 (7.1%)	0	1 (5.3%)				
Overall number of abnormal injection-site reactions		1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 3 of 4

Table 1.33 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	0	0	0				
	MILD	0	0	0				
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Bruising	ANY	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]	
	MILD	0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -1.0000]	
	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				
Overall number of abnormal injection-site reactions		0	1 (100.0%)	1 (25.0%)	0.0476 [0.0006, 3.7328]	0.1667 [0.0111, 2.5135] 0.0833	-1.0000 [-1.0000, -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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 4 of 4

Table 1.34 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=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	5 (7.0%)	3 (7.9%)	8 (7.3%)	0.8864 [0.2035, 3.8610]	0.8926 [0.2244, 3.5505] 0.8720	-0.0085 [-0.1141, 0.0971]	0.6404
	MILD	4 (5.6%)	3 (7.9%)	7 (6.4%)	0.6987 [0.1501, 3.2525]	0.7129 [0.1681, 3.0245] 0.6467	-0.0228 [-0.1247, 0.0791]	0.7795
	MODERATE	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
	SEVERE	0	0	0				
Bruising	ANY	2 (2.8%)	2 (5.3%)	4 (3.7%)	0.5174 [0.0698, 3.8381]	0.5319 [0.0782, 3.6173] 0.5167	-0.0247 [-0.1054, 0.0560]	0.9696
	MILD	2 (2.8%)	1 (2.6%)	3 (2.8%)	1.0749 [0.0943, 12.2577]	1.0732 [0.0985, 11.6866] 0.9540	0.0019 [-0.0619, 0.0657]	0.9734
	MODERATE	0	1 (2.6%)	1 (0.9%)	0.1636 [0.0062, 4.2892]	0.1786 [0.0077, 4.1198] 0.1649	-0.0266 [-0.0778, 0.0246]	0.9738
	SEVERE	0	0	0				
Swelling	ANY	2 (2.8%)	4 (10.5%)	6 (5.5%)	0.2393 [0.0418, 1.3692]	0.2648 [0.0516, 1.3590] 0.0886	-0.0779 [-0.1826, 0.0268]	0.2087

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022
v9.4 26MAY2023:14:17 Page 1 of 4

Table 1.34 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=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Swelling	MILD	2 (2.8%)	4 (10.5%)	6 (5.5%)	0.2393 [0.0418, 1.3692]	0.2648 [0.0516, 1.3590] 0.0886	-0.0779 [-0.1826, 0.0268]	0.2087
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Other	ANY	1 (1.4%)	3 (7.9%)	4 (3.7%)				0.5561
Overall number of abnormal injection-site reactions		6 (8.5%)	9 (23.7%)	15 (13.8%)	0.3093 [0.1029, 0.9296]	0.3581 [0.1368, 0.9379] 0.0290	-0.1525 [-0.3043, -0.0007]	0.0992

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 2 of 4

Table 1.34 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Redness	ANY	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.4881 [0.0624, 3.8205]	0.5222 [0.0798, 3.4159] 0.4968	-0.0630 [-0.2579, 0.1318]	
	MILD	2 (6.9%)	2 (13.3%)	4 (9.1%)	0.4881 [0.0624, 3.8205]	0.5222 [0.0798, 3.4159] 0.4968	-0.0630 [-0.2579, 0.1318]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Bruising	ANY	2 (6.9%)	0	2 (4.5%)	3.1481 [0.1342, 73.8566]	2.8125 [0.1510, 52.3815] 0.2905	0.0704 [-0.0227, 0.1634]	
	MILD	2 (6.9%)	0	2 (4.5%)	3.1481 [0.1342, 73.8566]	2.8125 [0.1510, 52.3815] 0.2905	0.0704 [-0.0227, 0.1634]	
	MODERATE	0	0	0				
	SEVERE	0	0	0				
Swelling	ANY	3 (10.3%)	1 (6.7%)	4 (9.1%)	1.7500 [0.1514, 20.2314]	1.6000 [0.1971, 12.9903] 0.6585	0.0396 [-0.1212, 0.2004]	
	MILD	3 (10.3%)	1 (6.7%)	4 (9.1%)	1.7500 [0.1514, 20.2314]	1.6000 [0.1971, 12.9903] 0.6585	0.0396 [-0.1212, 0.2004]	
	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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:17 Page 3 of 4

Table 1.34 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)	Daily rhGH (N=15)	Total (N=44)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Other	ANY	1 (3.4%)	1 (6.7%)	2 (4.5%)				
Overall number of abnormal injection-site reactions		6 (20.7%)	2 (13.3%)	8 (18.2%)	1.8833 [0.2942, 12.0579]	1.5889 [0.3926, 6.4305]	0.0777 [-0.1342, 0.2896]	
						0.5128		

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:17 Page 4 of 4

Table 1.36 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=42) | Daily rhGH (N=22) | Total (N=64) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Pain	ANY	10 (23.8%)	3 (13.6%)	13 (20.3%)	1.9792 [0.4834, 8.1030]	1.7460 [0.5351, 5.6971] 0.3405	0.1017 [-0.0910, 0.2945]	0.9875
	HURTS LITTLE BIT	5 (11.9%)	2 (9.1%)	7 (10.9%)	1.3514 [0.2401, 7.6049]	1.3095 [0.2761, 6.2105] 0.7339	0.0281 [-0.1269, 0.1831]	0.5722
	HURTS LITTLE MORE	2 (4.8%)	1 (4.5%)	3 (4.7%)	1.0500 [0.0899, 12.2640]	1.0476 [0.1005, 10.9233] 0.9692	0.0022 [-0.1061, 0.1104]	0.6626
	HURTS EVEN MORE	0	0	0				0.9776
	HURTS WHOLE LOT	2 (4.8%)	0	2 (3.1%)	2.7778 [0.1277, 60.4271]	2.6744 [0.1340, 53.3879] 0.3022	0.0476 [-0.0168, 0.1120]	0.9972
	HURTS WORST	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9748
Itching	ANY	2 (4.8%)	5 (22.7%)	7 (10.9%)	0.1700 [0.0300, 0.9639]	0.2095 [0.0442, 0.9937] 0.0300	-0.1797 [-0.3662, 0.0069]	0.0432
	ITCHES A LITTLE	1 (2.4%)	5 (22.7%)	6 (9.4%)	0.0829 [0.0090, 0.7637]	0.1048 [0.0130, 0.8420] 0.0085	-0.2035 [-0.3845, -0.0224]	0.0183

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 1 of 4

Table 1.36 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=42) | Daily rhGH (N=22) | Total (N=64) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Itching	ITCHES EVEN MORE	1 (2.4%)	0	1 (1.6%)	1.6265 [0.0636, 41.5922]	1.6047 [0.0681, 37.8342] 0.4692	0.0238 [-0.0223, 0.0699]	0.9747
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		10 (23.8%)	6 (27.3%)	16 (25.0%)	0.8333 [0.2569, 2.7029]	0.8730 [0.3655, 2.0855] 0.7630	-0.0346 [-0.2610, 0.1917]	0.4100

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 2 of 4

Table 1.36 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Pain	ANY	13 (22.4%)	4 (12.9%)	17 (19.1%)	1.9500 [0.5769, 6.5918]	1.7371 [0.6187, 4.8770] 0.2796	0.0951 [-0.0644, 0.2546]	
	HURTS LITTLE BIT	9 (15.5%)	2 (6.5%)	11 (12.4%)	2.6633 [0.5380, 13.1847]	2.4052 [0.5537, 10.4482] 0.2183	0.0907 [-0.0365, 0.2178]	
	HURTS LITTLE MORE	2 (3.4%)	2 (6.5%)	4 (4.5%)	0.5179 [0.0693, 3.8673]	0.5345 [0.0791, 3.6124] 0.5171	-0.0300 [-0.1284, 0.0684]	
	HURTS EVEN MORE	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]	
	HURTS WHOLE LOT	1 (1.7%)	0	1 (1.1%)	1.6435 [0.0650, 41.5450]	1.6271 [0.0682, 38.7977] 0.4647	0.0172 [-0.0163, 0.0507]	
	HURTS WORST	0	0	0				
Itching	ANY	7 (12.1%)	2 (6.5%)	9 (10.1%)	1.9902 [0.3875, 10.2213]	1.8707 [0.4134, 8.4660] 0.4050	0.0562 [-0.0643, 0.1766]	
	ITCHES A LITTLE	6 (10.3%)	1 (3.2%)	7 (7.9%)	3.4615 [0.3975, 30.1409]	3.2069 [0.4040, 25.4549] 0.2372	0.0712 [-0.0289, 0.1712]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 3 of 4

Table 1.36 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=58)	Daily rhGH (N=31)	Total (N=89)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Itching	ITCHES EVEN MORE	1 (1.7%)	1 (3.2%)	2 (2.2%)	0.5263 [0.0318, 8.7145]	0.5345 [0.0346, 8.2551] 0.6507	-0.0150 [-0.0857, 0.0556]	
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		14 (24.1%)	5 (16.1%)	19 (21.3%)	1.6545 [0.5343, 5.1238]	1.4966 [0.5944, 3.7678] 0.3824	0.0801 [-0.0899, 0.2501]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

Table 1.37 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a] OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	Subgroup Interaction p-value
Pain	ANY	19 (21.8%)	7 (15.6%)	26 (19.7%)	1.5162 [0.5846, 3.9324]	1.4037 [0.6380, 3.0885] 0.3934	0.0628 [-0.0742, 0.1997]	0.9710
	HURTS LITTLE BIT	11 (12.6%)	4 (8.9%)	15 (11.4%)	1.4832 [0.4450, 4.9439]	1.4232 [0.4800, 4.2199] 0.5214	0.0376 [-0.0711, 0.1464]	0.9767
	HURTS LITTLE MORE	3 (3.4%)	3 (6.7%)	6 (4.5%)	0.5009 [0.0971, 2.5830]	0.5164 [0.1079, 2.4710] 0.4030	-0.0322 [-0.1147, 0.0503]	0.9760
	HURTS EVEN MORE	1 (1.1%)	0	1 (0.8%)	1.6105 [0.0633, 40.9821]	1.5918 [0.0672, 37.7117] 0.4705	0.0115 [-0.0109, 0.0340]	0.9786
	HURTS WHOLE LOT	3 (3.4%)	0	3 (2.3%)	2.1251 [0.2279, 19.8148]	2.0734 [0.2359, 18.2239] 0.2110	0.0344 [-0.0039, 0.0727]	0.9750
	HURTS WORST	1 (1.1%)	0	1 (0.8%)	1.5974 [0.0622, 40.9986]	1.5750 [0.0670, 37.0024] 0.4739	0.0114 [-0.0109, 0.0338]	0.9786
Itching	ANY	9 (10.3%)	7 (15.6%)	16 (12.1%)	0.6372 [0.2250, 1.8049]	0.6656 [0.2613, 1.6956] 0.3884	-0.0521 [-0.1780, 0.0738]	0.9989
	ITCHES A LITTLE	7 (8.0%)	6 (13.3%)	13 (9.8%)	0.5867 [0.1912, 1.8003]	0.6041 [0.2101, 1.7367] 0.3373	-0.0529 [-0.1705, 0.0647]	0.9988

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 1 of 3

Table 1.37 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=87)	Daily rhGH (N=45)	Total (N=132)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Itching	ITCHES EVEN MORE	2 (2.3%)	1 (2.2%)	3 (2.3%)	1.0371 [0.0915, 11.7510]	1.0364 [0.0959, 11.1985] 0.9767	0.0008 [-0.0526, 0.0542]	0.9999
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		20 (23.0%)	11 (24.4%)	31 (23.5%)	0.9220 [0.3966, 2.1432]	0.9399 [0.4950, 1.7849] 0.8513	-0.0147 [-0.1683, 0.1389]	0.9681

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 2 of 3

Table 1.37 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=13)	Daily rhGH (N=8)	Total (N=21)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Pain	ANY	4 (30.8%)	0	4 (19.0%)	4.4943 [0.4152, 48.6502]	3.1741 [0.4327, 23.2846] 0.0980	0.3081 [0.0571, 0.5591]	
	HURTS LITTLE BIT	3 (23.1%)	0	3 (14.3%)	3.4405 [0.3098, 38.2094]	2.6666 [0.3538, 20.0978] 0.1624	0.2323 [0.0029, 0.4617]	
	HURTS LITTLE MORE	1 (7.7%)	0	1 (4.8%)	2.0526 [0.0718, 58.6520]	1.9091 [0.0898, 40.5985] 0.4386	0.0758 [-0.0682, 0.2197]	
	HURTS EVEN MORE	0	0	0				
	HURTS WHOLE LOT	0	0	0				
	HURTS WORST	0	0	0				
Itching								
	ANY	0	0	0				
	ITCHES A LITTLE	0	0	0				
	ITCHES EVEN MORE	0	0	0				
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		4 (30.8%)	0	4 (19.0%)	4.4943 [0.4152, 48.6502]	3.1741 [0.4327, 23.2846] 0.0980	0.3081 [0.0571, 0.5591]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 3 of 3

Table 1.38 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value[c]	RD [95%-CI] [b]	
Pain	ANY	3 (12.0%)	2 (15.4%)	5 (13.2%)	0.7660 [0.1163, 5.0446]	0.7864 [0.1460, 4.2358] 0.7799	-0.0330 [-0.2725, 0.2065]	0.2775
	HURTS LITTLE BIT	1 (4.0%)	2 (15.4%)	3 (7.9%)	0.2400 [0.0205, 2.8046]	0.2621 [0.0260, 2.6480] 0.2293	-0.1139 [-0.3269, 0.0990]	0.0571
	HURTS LITTLE MORE	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9712
	HURTS EVEN MORE	1 (4.0%)	0	1 (2.6%)	1.7273 [0.0638, 46.7676]	1.6667 [0.0746, 37.2138] 0.4669	0.0405 [-0.0368, 0.1177]	0.9727
	HURTS WHOLE LOT	0	0	0				0.9786
	HURTS WORST	0	0	0				0.9815
Itching	ANY	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5192 [0.0338, 7.9646]	0.5192 [0.0338, 7.9815] 0.6323	-0.0375 [-0.2067, 0.1317]	0.8471
	ITCHES A LITTLE	1 (4.0%)	1 (7.7%)	2 (5.3%)	0.5192 [0.0338, 7.9646]	0.5192 [0.0338, 7.9815] 0.6323	-0.0375 [-0.2067, 0.1317]	0.9018
	ITCHES EVEN MORE	0	0	0				0.9999
	ITCHES WORSE	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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 1 of 4

Table 1.38 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=25)	Daily rhGH (N=13)	Total (N=38)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Overall number of abnormal injection-site reactions		3 (12.0%)	2 (15.4%)	5 (13.2%)	0.7660 [0.1163, 5.0446]	0.7864 [0.1460, 4.2358] 0.7799	-0.0330 [-0.2725, 0.2065]	0.5933

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 2 of 4

Table 1.38 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

					Lonapegsomatropin vs. Daily rhGH [a]			
Symptom	Severity	TransCon hGH (N=75)	Daily rhGH (N=40)	Total (N=115)	OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	Subgroup Interaction p-value
Pain	ANY	20 (26.7%)	5 (12.5%)	25 (21.7%)	2.5394 [0.8742, 7.3767]	2.1330 [0.8648, 5.2608] 0.0821	0.1416 [-0.0018, 0.2850]	
	HURTS LITTLE BIT	13 (17.3%)	2 (5.0%)	15 (13.0%)	3.9771 [0.8524, 18.5565]	3.4679 [0.8228, 14.6171] 0.0633	0.1234 [0.0142, 0.2326]	
	HURTS LITTLE MORE	3 (4.0%)	3 (7.5%)	6 (5.2%)	0.5152 [0.0994, 2.6705]	0.5326 [0.1119, 2.5352] 0.4250	-0.0350 [-0.1281, 0.0581]	
	HURTS EVEN MORE	0	0	0				
	HURTS WHOLE LOT	3 (4.0%)	0	3 (2.6%)	2.2062 [0.2357, 20.6518]	2.1421 [0.2446, 18.7570] 0.2036	0.0399 [-0.0044, 0.0842]	
	HURTS WORST	1 (1.3%)	0	1 (0.9%)	1.6567 [0.0642, 42.7517]	1.6286 [0.0697, 38.0615] 0.4669	0.0133 [-0.0126, 0.0392]	
Itching	ANY	8 (10.7%)	6 (15.0%)	14 (12.2%)	0.6839 [0.2229, 2.0981]	0.7117 [0.2623, 1.9309] 0.5026	-0.0433 [-0.1758, 0.0892]	
	ITCHES A LITTLE	6 (8.0%)	5 (12.5%)	11 (9.6%)	0.6225 [0.1829, 2.1185]	0.6406 [0.2035, 2.0163] 0.4385	-0.0450 [-0.1670, 0.0770]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 3 of 4

Table 1.38 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=75)	Daily rhGH (N=40)	Total (N=115)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Itching	ITCHES EVEN MORE	2 (2.7%)	1 (2.5%)	3 (2.6%)	1.0702 [0.0941, 12.1692]	1.0685 [0.0993, 11.4975] 0.9567	0.0017 [-0.0589, 0.0623]	
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		21 (28.0%)	9 (22.5%)	30 (26.1%)	1.3396 [0.5454, 3.2904]	1.2436 [0.6308, 2.4517] 0.5266	0.0548 [-0.1094, 0.2191]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 4 of 4

Table 1.39 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Pain	ANY	19 (22.9%)	7 (14.9%)	26 (20.0%)	1.6990 [0.6556, 4.4035]	1.5389 [0.6991, 3.3872] 0.2755	0.0803 [-0.0559, 0.2164]	0.9990
	HURTS LITTLE BIT	12 (14.5%)	4 (8.5%)	16 (12.3%)	1.8203 [0.5545, 5.9756]	1.7051 [0.5838, 4.9798] 0.3195	0.0601 [-0.0503, 0.1705]	0.9988
	HURTS LITTLE MORE	4 (4.8%)	3 (6.4%)	7 (5.4%)	0.7428 [0.1588, 3.4758]	0.7549 [0.1755, 3.2483] 0.7072	-0.0156 [-0.0993, 0.0681]	1.0000
	HURTS EVEN MORE	0	0	0				0.9991
	HURTS WHOLE LOT	2 (2.4%)	0	2 (1.5%)	1.7481 [0.1768, 17.2886]	1.7211 [0.1841, 16.0899] 0.2884	0.0240 [-0.0089, 0.0570]	0.9998
	HURTS WORST	1 (1.2%)	0	1 (0.8%)	1.6849 [0.0656, 43.2815]	1.6579 [0.0706, 38.9187] 0.4622	0.0117 [-0.0114, 0.0348]	0.9997
Itching	ANY	7 (8.4%)	7 (14.9%)	14 (10.8%)	0.5449 [0.1842, 1.6124]	0.5704 [0.2111, 1.5413] 0.2579	-0.0645 [-0.1855, 0.0564]	0.9985
	ITCHES A LITTLE	6 (7.2%)	6 (12.8%)	12 (9.2%)	0.5495 [0.1732, 1.7432]	0.5677 [0.1920, 1.6785] 0.2937	-0.0559 [-0.1694, 0.0577]	0.9997

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 1 of 4

Table 1.39 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=83)	Daily rhGH (N=47)	Total (N=130)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Itching	ITCHES EVEN MORE	1 (1.2%)	1 (2.1%)	2 (1.5%)	0.5778 [0.0347, 9.6309]	0.5870 [0.0383, 9.0067] 0.7011	-0.0087 [-0.0558, 0.0384]	0.9991
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		20 (24.1%)	11 (23.4%)	31 (23.8%)	1.0372 [0.4485, 2.3985]	1.0284 [0.5409, 1.9553] 0.9322	0.0067 [-0.1461, 0.1594]	0.9987

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:20 Page 2 of 4

Table 1.39 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)

					Lonapegsomatropin vs. Daily rhGH [a]			
Symptom	Severity	TransCon hGH (N=14)	Daily rhGH (N=5)	Total (N=19)	OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	Subgroup Interaction p-value
Pain	ANY	3 (21.4%)	0	3 (15.8%)	2.0976 [0.1844, 23.8596]	1.7960 [0.2425, 13.3040] 0.2581	0.2233 [0.0060, 0.4406]	
	HURTS LITTLE BIT	2 (14.3%)	0	2 (10.5%)	1.4275 [0.1208, 16.8721]	1.3467 [0.1693, 10.7131] 0.3919	0.1456 [-0.0392, 0.3305]	
	HURTS LITTLE MORE	0	0	0				
	HURTS EVEN MORE	0	0	0				
	HURTS WHOLE LOT	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]	
	HURTS WORST	0	0	0				
Itching	ANY	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]	
	ITCHES A LITTLE	0	0	0				
	ITCHES EVEN MORE	1 (7.1%)	0	1 (5.3%)	1.6667 [0.0477, 58.2811]	1.5000 [0.0838, 26.8551] 0.5271	0.0777 [-0.0623, 0.2177]	
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		3 (21.4%)	0	3 (15.8%)	2.0976 [0.1844, 23.8596]	1.7960 [0.2425, 13.3040] 0.2581	0.2233 [0.0060, 0.4406]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:20 Page 3 of 4

Table 1.39 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=3)	Daily rhGH (N=1)	Total (N=4)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Pain	ANY	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]	
	HURTS LITTLE BIT	0	0	0				
	HURTS LITTLE MORE	0	0	0				
	HURTS EVEN MORE	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]	
	HURTS WHOLE LOT	0	0	0				
	HURTS WORST	0	0	0				
Itching	ANY	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]	
	ITCHES A LITTLE	1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]	
	ITCHES EVEN MORE	0	0	0				
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		1 (33.3%)	0	1 (25.0%)	1.8000 [0.0408, 79.4237]	1.5000 [0.0995, 22.6218] 0.5637	0.3333 [-0.2001, 0.8668]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 4 of 4

Table 1.40 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=71)	Daily rhGH (N=38)	Total (N=109)	Lonapegsomatropin vs. Daily rhGH [a]			Subgroup Interaction p-value
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Pain	ANY	19 (26.8%)	7 (18.4%)	26 (23.9%)	1.6170 [0.6123, 4.2705]	1.4543 [0.6718, 3.1479] 0.3324	0.0838 [-0.0773, 0.2449]	0.9760
	HURTS LITTLE BIT	14 (19.7%)	4 (10.5%)	18 (16.5%)	2.0809 [0.6344, 6.8251]	1.8703 [0.6623, 5.2816] 0.2228	0.0918 [-0.0429, 0.2266]	0.9985
	HURTS LITTLE MORE	3 (4.2%)	3 (7.9%)	6 (5.5%)	0.5157 [0.0989, 2.6903]	0.5364 [0.1138, 2.5286] 0.4292	-0.0366 [-0.1342, 0.0611]	0.9695
	HURTS EVEN MORE	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9804
	HURTS WHOLE LOT	1 (1.4%)	0	1 (0.9%)	1.6897 [0.0663, 43.0859]	1.6667 [0.0705, 39.4042] 0.4602	0.0143 [-0.0133, 0.0418]	0.9959
	HURTS WORST	0	0	0				0.9724
Itching	ANY	8 (11.3%)	5 (13.2%)	13 (11.9%)	0.8470 [0.2625, 2.7325]	0.8600 [0.2988, 2.4757] 0.7783	-0.0185 [-0.1512, 0.1143]	0.3621
	ITCHES A LITTLE	7 (9.9%)	4 (10.5%)	11 (10.1%)	0.9335 [0.2633, 3.3094]	0.9376 [0.2882, 3.0506] 0.9139	-0.0066 [-0.1293, 0.1160]	0.9751

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:20 Page 1 of 4

Table 1.40 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

| | | TransCon hGH (N=71) | Daily rhGH (N=38) | Total (N=109) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
| | | | | | OR [95%-CI] [b] | RR [95%-CI] [b] P-value [c] | RD [95%-CI] [b] | |
Symptom	Severity							
Itching	ITCHES EVEN MORE	1 (1.4%)	1 (2.6%)	2 (1.8%)	0.5349 [0.0320, 8.9528]	0.5455 [0.0357, 8.3368] 0.6610	-0.0119 [-0.0693, 0.0456]	0.9785
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		20 (28.2%)	9 (23.7%)	29 (26.6%)	1.2634 [0.5113, 3.1217]	1.1909 [0.6019, 2.3563] 0.6133	0.0453 [-0.1266, 0.2171]	0.8515

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 2 of 4

Table 1.40 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) | Daily rhGH (N=15) | Total (N=44) | Lonapegsomatropin vs. Daily rhGH [a] | | | Subgroup Interaction p-value |
					OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	
Pain	ANY	4 (13.8%)	0	4 (9.1%)	6.6522 [0.3140, 140.9252]	5.0625 [0.3062, 83.6926] 0.1160	0.1408 [0.0144, 0.2672]	
	HURTS LITTLE BIT	0	0	0				
	HURTS LITTLE MORE	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]	
	HURTS EVEN MORE	0	0	0				
	HURTS WHOLE LOT	2 (6.9%)	0	2 (4.5%)	3.1481 [0.1342, 73.8566]	2.8125 [0.1510, 52.3815] 0.2905	0.0704 [-0.0227, 0.1634]	
	HURTS WORST	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]	
Itching	ANY	1 (3.4%)	2 (13.3%)	3 (6.8%)	0.2143 [0.0162, 2.8392]	0.2667 [0.0283, 2.5095] 0.2239	-0.0968 [-0.2764, 0.0829]	
	ITCHES A LITTLE	0	2 (13.3%)	2 (4.5%)	0.0839 [0.0035, 1.9997]	0.1125 [0.0060, 2.0953] 0.0475	-0.1320 [-0.3034, 0.0395]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022

v9.4 26MAY2023:14:20 Page 3 of 4

Table 1.40 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

					Lonapegsomatropin vs. Daily rhGH [a]			
Symptom	Severity	TransCon hGH (N=29)	Daily rhGH (N=15)	Total (N=44)	OR [95%-CI] [b]	RR [95%-CI] [b] P-value [c]	RD [95%-CI] [b]	Subgroup Interaction p-value
Itching	ITCHES EVEN MORE	1 (3.4%)	0	1 (2.3%)	1.7586 [0.0642, 48.1939]	1.6875 [0.0764, 37.2598] 0.4652	0.0352 [-0.0319, 0.1022]	
	ITCHES WORSE	0	0	0				
Overall number of abnormal injection-site reactions		4 (13.8%)	2 (13.3%)	6 (13.6%)	1.0909 [0.1525, 7.8020]	1.0667 [0.2466, 4.6138] 0.9324	0.0088 [-0.1884, 0.2060]	

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-cn-visen\adhoc\amnog_dossier\prog\t-maxsevsym-inj-pp-sub.sas
Data Extracted: 29Apr2022   v9.4 26MAY2023:14:20 Page 4 of 4