

Italfarmaco S.p.A. study no: DSC/13/2984/05

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Table 14.2.4.1 Summary of Reduction of GH Level < 2.5 (mcg/litre) and Normalization of IGF-1 (nmol/ml) at the End of the Treatment Period
(Intent-to-treat Analysis Set)

Period		Treatment			
		100 mcg Octreotide (N=41) n (%)	500 mcg ITF2984 (N=43) n (%)	1000 mcg ITF2984 (N=47) n (%)	2000 mcg ITF2984 (N=42) n (%)
1	Yes	0	0	1 (2.1)	4 (9.5)
	No	11 (26.8)	12 (27.9)	8 (17.0)	8 (19.0)
2	Yes	3 (7.3)	0	2 (4.3)	3 (7.1)
	No	9 (22.0)	8 (18.6)	10 (21.3)	8 (19.0)
3	Yes	1 (2.4)	1 (2.3)	0	4 (9.5)
	No	10 (24.4)	10 (23.3)	11 (23.4)	4 (9.5)
4	Yes	0	1 (2.3)	1 (2.1)	3 (7.1)
	No	7 (17.1)	10 (23.3)	10 (21.3)	8 (19.0)
Overall	Yes	4 (9.8)	2 (4.7)	4 (8.5)	14 (33.3)
	No	37 (90.2)	40 (93.0)	39 (83.0)	28 (66.7)

N = the number of subjects in the analysis set receiving the specified treatment.

n = the number of subjects with a measurement.

(%) = n/N*100.

Source: Listing 16.2.6.1

PROGRAM NAME:T_GHIGF_01.SAS

DATE OF RUN:12SEP2016

TIME OF RUN: 11:55:07

DATE OF EXTRACTION:25MAY2016