

From: Khurana, Taruna
Sent: Friday, November 18, 2016 11:41 AM
To: nadine_margaretten@merck.com
Cc: Steele, Matthew (Matthew.Steele@fda.hhs.gov); Sweeney, Colleen
Subject: STN 125592 Stats IR (11.18.16)

Hi Nadine,

We have the following request for information:

You submitted the post-hoc analyses of average Total Combined Rhinitis Score (TCRS) during the last 8 weeks of treatment by age subgroup for study P001 in the amendment STN 125592/0.10. The number of subjects by age subgroup you reported for the Full Analysis Set (FAS) showed some discrepancies with those from our analysis of the dataset ADEFF based on variable "AGE" (see Table 1 below). It is noticed that, in the dataset ADEFF, 9 subjects of age 17 years are categorized as "18 to <50" under variable AGERGR1 (5 subjects with MK-8237 and 4 subjects with Placebo). Additionally, one subject (with Placebo) of age 11 years is categorized as "12 to <18" under variable AGERGR1. Please clarify. Also, please verify and update the post-hoc analysis results accordingly for both FAS and the Per-Protocol Set, and please provide the updated dataset ADEFF with a variable for categorization of the age subgroups, i.e. 12 to <18 years, 18 to 65 years, and >65 years. Additionally, please verify and update other age related subgroup analyses accordingly, if needed.

Table 1: Number of subjects categorized into the age subgroups at randomization (Full Analysis Set)

Age subgroup		Number of subjects reported in Table 1 in STN 125592/0.10	Number of subjects based variable "AGE" in the dataset ADEFF
12 to <18 years	MK-8237 12 DU	76	81
	Placebo	84	87
18 to 65 years	MK-8237 12 DU	482	477
	Placebo	526	525
>65 years	MK-8237 12 DU	8	8
	Placebo	10	7

Please submit the information within one week. Let me know if you have any questions.

Thank you

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