

Addendum to sNDA22369 Supplement 010 Statistical Review

This is an addendum to the statistical review of NDA22369 supplement 010. The main purpose of this addendum is to correct the typo for the proportion of healthy adolescent who had at least 1-grade GEA improvement at Month 4 and its corresponding 95% confidence interval (CI) reported (b) (4) Table 12. In addition, the 95% CI for the overall population without adjusting for the stratification factor (age group) was also added to Table 12. The overall conclusion and recommendation of the statistical review remain the same.

(b) (4)

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The updated Table 12 is as follows.

Table 12: Proportion of Subjects Who Had at Least 1-Grade GEA Improvement at Month 4 (ITT)

Month 4	Bim 0.03%	Vehicle	p-value^a	Difference (95% CI)
Post Chemotherapy Pediatrics	11/13 (84.6%)	3/3 (100.0%)		-15.4% (-35.0%, 4.2%) ^b
Alopecia Areata Pediatrics	4/9 (44.4%)	2/6 (33.3%)		11.1% (-38.7%, 60.9%) ^b
Healthy Adolescent	19/26 (73.1%)	1/14 (7.1%)		65.9% (44.2%, 87.7%) ^b

^a P-value for between-group comparison is based on Cochran-Mantel-Haenszel test stratified by age group (5-11 versus 12-17 years). Difference and 95 % CI based on Mantel-Haenszel method stratified by age group using Greenland and Robins' 1985 formula.

^b Difference and 95 % CI based on normal approximation to binomial distribution without adjusting for the stratification factor – age group.

Source: Tables 11-2 and 14.5-12 of Study 192024-040 report, and statistical reviewer's calculation.

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