

ERRATA

Cisplatin/Epinephrine Injectable Gel

Background Document

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NDA 21-236

**Matrix Pharmaceutical, Inc.
34700 Campus Drive
Fremont, California 94555**

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Errata

p. 39, section 6.5.1, ¶1, line 8)

After sentence beginning “A total of 44 and 27 sites”, insert new sentence “Of these, 37 and 25 sites (studies 414 and 514, respectively) enrolled patients in strata 1 and 2.” The percentages cited in the following sentence refer to patients in strata 1 and 2 only.

p. 43, Table 19, last row

“Not available” count for Placebo Gel should be 12 (instead of 3)

p. 43, Table 20

Numbers shown are number of patients, not percentages. Percentages are shown below:

Table 20: Location of MTT and of All Tumors Treated in Blinded Treatment Phase by Study

Location	414-94-2				514-94-2			
	cDDP/epi Gel		Placebo Gel		cDDP/epi Gel		Placebo Gel	
Tumor(s) Treated	MTT	All	MTT	All	MTT	All	MTT	All
Total n (tumors)	n=62	n=160	n=24	n=36	n=57	n=67	n=35	n=44
Cervical	53%	62%	38%	44%	37%	37%	57%	57%
Oral cavity	13%	7%	8%	6%	42%	37%	23%	18%
Facial	21%	18%	29%	31%	11%	15%	17%	23%
Laryngopharyngeal	5%	2%	17%	11%	7%	6%	3%	2%
Nasopharyngeal	3%	1%	8%	6%	0	0	0	0
Cranial	3%	7%	0	0	4%	4%	0	0
Chest wall	2%	3%	0	0	0	0	0	0

p. 46, ¶1, line 1

"Prior to the protocol amendment, the median cumulative dose administered to the MTT..." should be "the median cumulative dose administered to the patient"

p. 46, Table 29, last row, 1st column

"No. (%) of visits where $\geq 80\%$ of assigned dose delivered" should read "No. (%) of patients having cumulative percentage of assigned dose administered to MTT $\geq 80\%$ " [i.e., ratio of cumulative dose administered to cumulative dose assigned at least 0.8]

p. 47, Table 30, last row

"No. (%) of visits where $\geq 80\%$ of assigned dose delivered" should read "No. (%) of patients having cumulative percentage of assigned dose administered to MTT $\geq 80\%$ " [i.e., ratio of cumulative dose administered to cumulative dose assigned at least 0.8] and row counts and percentages in the last three cells should be changed to:

Stratum 1		Stratum 2		Strata 1 and 2	
CDDP/epi gel	Placebo gel	CDDP/epi gel	Placebo gel	CDDP/epi gel	Placebo gel
	(no change)	(no change)	22 (73%)	77 (65%)	48 (81%)

p. 48, Table 32

All comparisons presented in Table 32 are stratified by study. The "Strata 1 & 2" comparison is stratified by both study and MTT stratum. There are no unstratified comparisons. Hence, the footnote symbols for the Stratum 1 and Stratum 2 p-values should be changed from "b" to "a" and footnote b should be deleted.

p. 49, Table 34, last row

Minimum observed durations were 30+, 36+, and 30+ for Stratum 1, Stratum 2, and Strata 1 & 2, respectively [see Tables A2-1 and A2-2 in Appendix 2 for complete list of durations].

p. 51, section 6.5.5.3, first sentence

"A total of 160 of the 178 patients ... went on to receive open label treatment with CDDP/epi gel after initial treatment in the blinded treatment phase."

should read

"A total of 160 of the 178 patients had MTTs treated with CDDP/epi gel during either the blinded treatment phase or the open label phase."

p. 59, Section 6.5.10, ¶1, line 4

"Data on the association of Patient Benefit and objective MTT response are provided in Tables 38 – 40 for studies 414, 514, and combined."

should read

"Data on the association of Patient Benefit and objective MTT response are provided in Table 48 for the studies combined."

p. 60, Table 48, footnote a

"Chi-squared test" should read "Exact Cochran-Mantel-Haenszel test"

p. 61, Table 49, footnote a

"Chi-squared p-value" should read "Exact Cochran-Mantel-Haenszel p-value"

p. 61, Table 51, Placebo Gel column

57/59 should read 5/59

p. 61, Table 51, footnote a

"Exact Cochran-Mantel-Haenszel test; chi-squared p-value <0.005 for association of this outcome with MTT response."

should read

"Exact Cochran-Mantel-Haenszel test; exact Cochran-Mantel-Haenszel p-value 0.005 for association of this outcome with MTT response."

p. 63, first sentence

"87 patients" should read "88 patients"; as discussed below, the patient who did not receive study medication, although the syringe was inserted, was included in safety analyses

p. 64, Table 52

Hemorrhage [sic] for Placebo Gel, Severe should be 1 (1%) (instead of 0 (0%))

p. 69, last paragraph, second sentence

"Fifty percent of the group randomized to CDDP/epi gel experienced at least one clinically significant increase in blood pressure during dosing."

should read

"Sixty-six percent of the group randomized to CDDP/epi gel experienced at least one clinically significant increase in blood pressure during dosing." [Overall incidence during the treatment phase was 99/150 (NDA T-14.3-14).]

p. 73, Table 60, missing footnote for footnote symbol c

c: includes decreased hearing and hearing loss.

Appendix 1, p. 7, section 6, line 6

"p=0.047" should be "p=0.046" [see Table 42]

Appendix 2, p. 7, Table A2-5

Treatment Group column should read "Placebo Gel" for patients 2064, 5277, 2159 and 5302

Appendix 2, p. 8, Table A2-6

Treatment Group column should read "Placebo Gel" for patient 5495

Appendix 3, p. 4, Table A3-8

column heading "Goal type" should read "Primary goal type"

Appendix 3, p. 6, ¶1, line 1

"While the median number of blinded treatment visits was for" should read "While the median number of blinded treatment visits was four"

Appendix 4, p. 1, Table A4-2

“Other” should be 7 (23%) (instead of 7 (2%))

Appendix 4, p. 4, Table A4-7

Stratum 3, last column, Exact p should be 0.27 (instead of 0.15)

Stratum 1, Placebo Gel, 95% CI should be 0.087-18% (instead of 0.87 – 18%)