

Errata – FDA Briefing document for NDA 208587

Oncologic Drugs Advisory Committee Meeting

May 24, 2017

Page	Change
Page 5, Section 2	Paragraph 1, lines 3-4: Delete "'s age 5 years and older". Paragraph 2, line 1: Delete "open-label". Paragraph 2, line 7: Delete "geographic region" replace with "by study site". Paragraph 3, line 5: After "Toradol (ketorolac)." insert the sentence- "The occurrences of acute chest syndrome, priapism, and splenic sequestration were also considered sickle cell crises even if the symptoms were not painful enough to require narcotics."
Page 6	Paragraph 1, line 4: Delete "crises over"; replace with "rates of crises per". Paragraph 1, line 5: Delete "crises".
Page 9, Section 3.3	Paragraph 1, line 2: Delete "Table 3"; replace with "Table 1".
Page 10	Table 1, last row: Delete "FDA expressed concern about ...".
Page 11, Section 4.1	Paragraph 1, line 1: Delete "open-label".
Page 12, Section 4.1.1.	Line 1: Delete "298"; replace with "230".
Page 18	Paragraph 1, line 2: Delete "62%"; replace with "57%".
Page 19	Paragraph 4, line 6: Delete "a 0.048"; replace with "0.045".
Page 29	Table 14, row 2, column 1: Delete "Table 5"; replace with "Table 9". Table 14, row 3, column 1: Delete "Table 5"; replace with "Table 9". Table 14, row 4, column 1: Delete "Table 5"; replace with "Table 9". Table 14, row 4, column 1: Delete "model also controlling for patient age and baseline crisis count". Paragraph 2, line 1: Delete "16"; replace with "15".
Page 33	Table 18: Delete asterisks from column 1, row 2 and last row. Table 18, row 4, Column 3: insert "111 (100.0)". Table 18, row 4, Column 4: insert "298 (100.0)".
Page 37	Table 21, row 1, column 2: Delete "107"; replace with "187". Table 21, row 1, column 3: Delete "63"; replace with "111".
Page 42	Table 26: Delete entire Table. Replace with Table 26 on page 2 of this document.
Page 44	Paragraph 3, line 1: Delete "Table 15", replace with "Table 27".
Page 45	Table 27, row 3, column 4: Insert "65 (100.0)". Section 5, paragraph 1, line 1: Delete 230, replace with "229".
Page 46	Paragraph 2, line 3: Delete "0.048"; replace with "0.045".

Table 26: TEAEs by Age group (≤ 18 years and > 18 years), (Safety Population)

TEAEs ($\geq 10\%$) in Subjects ≤ 18 years				
	L-glutamine (N = 80)		Placebo (N = 48)	
	Number of subjects	%	Number of subjects	(%)
Sickle cell anemia with crisis	67	83.75	42	87.50
Constipation	25	31.25	12	25.00
Pyrexia	22	27.50	23	47.92
Headache	21	26.25	12	25.0
Cough	20	25.00	13	27.08
Pain in extremity	18	22.50	4	8.33
Back pain	17	21.25	2	4.17
Abdominal pain	15	18.75	6	12.50
Upper respiratory tract infection	14	17.50	13	27.08
Acute chest syndrome	13	16.25	14	29.17
Nausea	13	16.25	11	22.92
Arthralgia	12	15.00	8	16.67
Chest pain	12	15.00	7	14.58
Nasal congestion	11	13.75	4	8.33
Vomiting	11	13.75	8	16.67
Oropharyngeal pain	10	12.50	7	14.58
Ocular icterus	9	11.25	5	10.42
Pruritus	9	11.25	4	8.33
Abdominal pain upper	8	10.00	3	6.25
Diarrhea	8	10.00	3	6.25
TEAEs ($\geq 10\%$) in Subjects >18 years				
	L-glutamine (N = 107)		Placebo (N = 63)	
	Number of subjects	(%)	Number of subjects	%
Sickle cell anemia with crisis	87	81.31	55	87.30
Nausea	23	21.5	5	7.94
Constipation	15	14.02	8	12.70
Headache	14	13.08	5	7.94
Vomiting	13	12.15	6	9.52
Pneumonia	13	12.15	12	19.05
Upper respiratory tract infection	12	11.21	7	11.11
Chest pain	11	10.28	3	4.76
Abdominal pain, upper	11	10.28	5	7.94