Daiichi Sankyo, Inc.
Oncologic Drugs Advisory Committee Meeting
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Errata for the Sponsor Briefing Document
Quizartinib
NDA 212166

AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION

Pages 30 and 106: Azacytidine should be azacitidine.

Figure 3.5 (Page 37): Figure 3.5 is a composite of two figures that should have been identified as follows: Top panel is reprinted from Galanis A, et al. Crenolanib is a potent inhibitor of FLT3 with activity against resistance-conferring point mutants. *Blood*. 2014;123:94-100. Bottom panel is reprinted from Galanis A, Levis M. Inhibition of c-Kit by tyrosine kinase inhibitors. *Haematologica.* 2015;100(3):e77-79.

Figure 3.5: Quizartinib Is Associated With Selective Inhibition of c-Kit

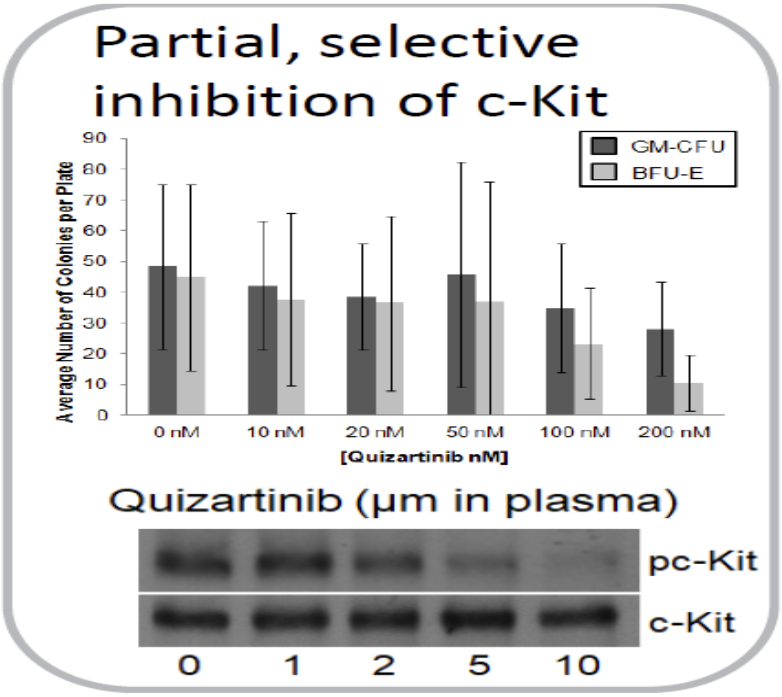


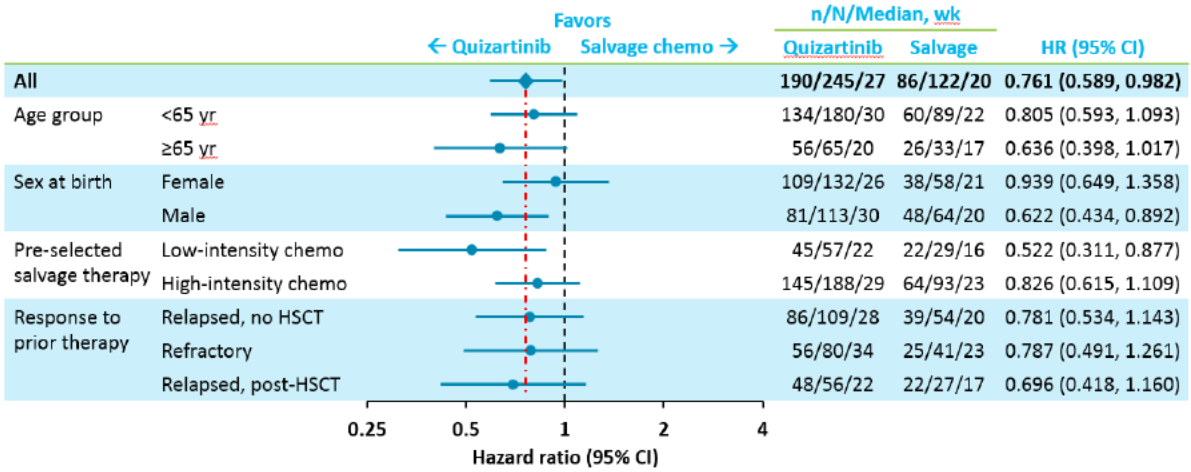
Table 9.1 (Page 65): Dose escalation for the quizartinib 30 mg starting dose has been corrected from 62.3 to 63.2 in this table.

Table 9.1: Results from Study 2689-CL-2004

	Patients, n	
	Quizartinib 30 mg starting dose (n=38)	**Quizartinib 60 mg starting dose (n=38)**
CRc rate, %	47.4	47.4
Dose escalation, %	63.2 (to 60 mg)	19.4 (to 90 mg)
Median duration of CRc, wk (95% CI)	4.2 (2.1, 9.7)	9.1 (4.1, 22.3)
PR rate, %	13.2	23.7
Transplant rate, %	31.6	42.1
Median OS, wk	20.9	27.3

Figure 9.4 (Page 73): The low-intensity chemo quizartinib numbers have been corrected from 45/77/22 to 45/57/22 in this figure.

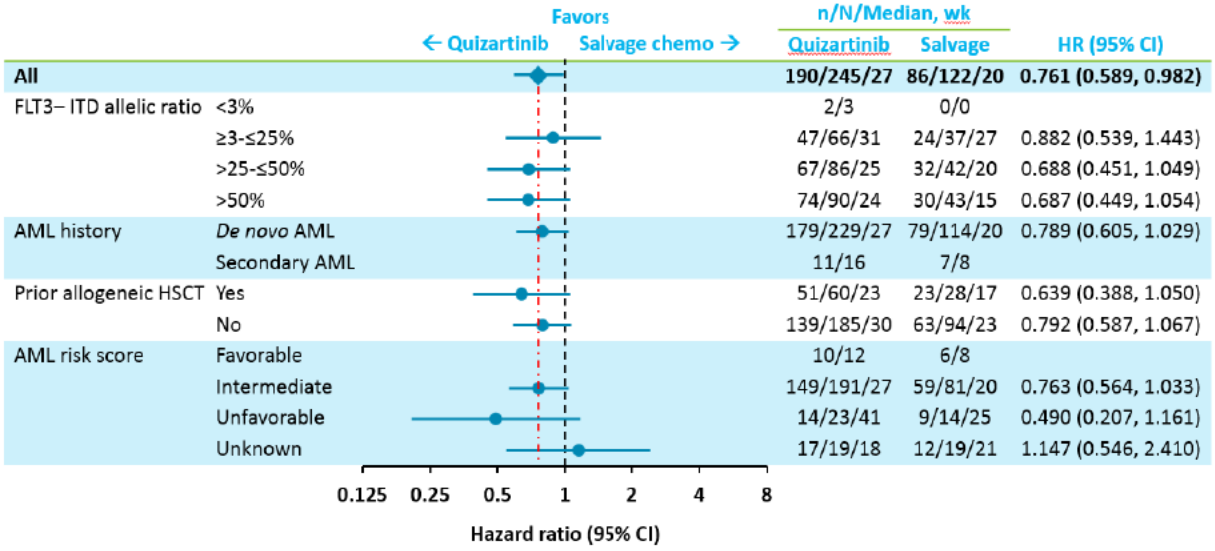
Figure 9.4: Forest Plot of Overall Survival by Prespecified Subgroups (Age, Sex, Preselected Salvage Therapy, Response to Prior Therapy): ITT Analysis Set



Notes: HR is obtained from unstratified Cox PH model.
Source: Study AC220-007 Figure 14.2.1.5.

Figure 9.5 (Page 73): The word allogenic has been corrected to allogeneic within the figure.

Figure 9.5: Forest Plot of Overall Survival by Prespecified Subgroups (FLT3-ITD Allelic Ratio, AML History, Prior Allogeneic HSCT, AML Risk Score): ITT Analysis Set



Notes: For subgroups with less than 30 patients, only the number of patients with/without events are presented.
HR is obtained from unstratified Cox PH model.
Source: AC220-007 Figure 14.2.1.5.

Table 9.8 (Page 78): Under the column heading Baseline Status, in the last row of this table, RBC transfusions has been corrected to PLT transfusions.

Table 9.8: Transfusion Independence Rate During Study Treatment Period of Quizartinib: Safety Analysis Set

	Quizartinib Monotherapy (N=241)		
Baseline Status	**Patients, n**	**Transfusion-independent Post-baseline, n (%)**	**Median, Mean (SD) for Transfusion-Independent Days[a]**
Any transfusions			
Dependent	205	46 (22.4)	185.5, 255 (216.6)
Independent	36	20 (55.6)	114.5, 208 (203.1)
RBC transfusions			
Dependent	196	45 (23.0)	150.0, 256 (231.7)
Independent	45	27 (60.0)	117.0, 194 (180.9)
PLT transfusions			
Dependent	176	48 (27.3)	134.5, 250 (231.5)
Independent	65	43 (66.2)	111.0, 172 (171.3)

Notes: Transfusion dependence at baseline was defined as transfusion within ±28 days to first dose of quizartinib. Transfusion independence post-baseline was defined as any post-baseline period of 56 days without a transfusion during study treatment period.
[a]The maximum interval without transfusion (in days) during the period was considered for each patient. Days 1-28 in both baseline dependence window and post-baseline independent window were considered.

Table 9.10 (Page 81): Under the main heading Quizartinib Monotherapy and under the column heading Treatment-Related, the row Any TESAE Grade ≥4 has been corrected from 18 (75) to 18 (7.5).

Table 9.10: Overview of Number (%) of Patients Reporting TEAEs: Safety Analysis Set

AE Category	Quizartinib Monotherapy (n=241), n (%)		Salvage Chemotherapy (n=94), n (%)	
	All	Treatment-Related	All	Treatment-Related
Any TEAE	238 (98.8)	205 (85.1)	93 (98.9)	66 (70.2)
Grade ≥3	211 (87.6)	154 (63.9)	74 (78.7)	48 (51.1)
Grade ≥4	143 (59.3)	93 (38.6)	51 (54.3)	35 (37.2)
Any TESAE	168 (69.7)	64 (26.6)	37 (39.4)	15 (16.0)
Grade ≥3	151 (62.7)	60 (24.9)	34 (36.2)	13 (13.8)
Grade ≥4	61 (25.3)	18 (7.5)	20 (21.3)	8 (8.5)
Outcome of death	36 (14.9)	9 (3.7)	11 (11.7)	4 (4.3)
Associated with study drug discontinuation	44 (18.3)	17 (7.1)	1 (1.1)	0 (0.0)
Associated with study drug interruption	84 (34.9)	59 (24.5)	1 (1.1)	1 (1.1)
Associated with dose reduction	52 (21.6)	42 (17.4)	1 (1.1)	1 (1.1)

Source: Study AC220-007 Table 14.3.1.1 and Table 14.3.1.20a

Figure 9.8 (Page 92): Should state data from these 60 patients corrected from 98 patients.

Data from these 60 patients allowed a within-subject evaluation of the concentration-QTc (C-QTc) relationship in the presence and absence of QTc-prolonging drugs.

Figure 9.8: QTcF vs Quizartinib Concentration for Patients Who Received QT-Prolonging Drugs (n=60)