Errata to Amgen's Briefing Document issued for the Oncologic Drugs Advisory Committee (ODAC) meeting scheduled for 05 October 2023. The erroneous text is identified by a strikethrough, with correction following in bold, unless otherwise specified.

1. Page 69

During the course of the study, **while performing event projection to determine event-driven analysis timing,** ~~the imaging vendor~~ **Amgen** ~~identified~~ **discovered** a discrepancy between the COP-based and BICR-based progression events**, and notified the imaging vendor**. **Based on this finding, and** ~~l~~**i**n accordance with the imaging charter, the imaging vendor undertook ~~a review~~ **an investigation** of the discordant cases to identify a root cause for the discordance and to assure the quality of the data.

2. Page 52, Table 8 was updated as a result of a discrepancy in the confirmation of progression (COP) data submitted to FDA, a minor numerical correction is needed for the two-stage approach adjusted pre-specified overall survival sensitivity analysis hazard ratio. The corrected COP data do not affect the conclusions of the survival sensitivity analysis which have been submitted to FDA to date.

Table 8. Overall Survival – Sensitivity Analysis Adjusting for Crossover (Full Analysis Set) (CodeBreaK 200 – PFS Primary Analysis)

	Sotorasib (N = 171)	Docetaxel (N = 174)	Treatment Difference
RPSFTM adjusted			
Events/subjects after crossover adjustment (%)	109/171 (63.7)	94/174 (54.0)	
Acceleration Factor (95% CI) [a]			0.989 (0.668, 1.522)
Hazard Ratio (95% CI) [b]			1.010 (0.660, 1.492)
IPCW adjusted			
Events/subjects after crossover adjustment (%)	109/171 (63.7)	77/174 (44.3)	
Hazard Ratio (95% CI) [b]			0.990 (0.733, 1.337)
Two-stage approach adjusted			
Events/subjects after crossover adjustment (%)	109/171 (63.7)	75/174 (43.1)	
Acceleration Factor (95% CI) [c]			1.~~731~~ **798** (0.~~799~~**821**, 3.~~749~~**936**)
Hazard Ratio (95% CI) [b]			0.~~920~~ **889** (0.~~409~~**350**, 1.~~300~~**294**)

The data is merged by the as-is snapshot dated ~~01SEP2023~~ **13SEP2023** for the updated Confirmation Of Progression (COP) data filtered back to the PA DCO of 02AUG2022, and the rest of the ADaM datasets from the PA clean snapshot dated 23AUG2022.
N = Number of patients in the analysis set. RPSFTM = Rank Preserving Structural Failure Time Model. IPCW = Inverse Probability of Censoring Weighting.
Randomization stratification factors are number of prior lines of therapy in advanced disease (1 vs 2 vs > 2), race (Asian vs non-Asian), and history of CNS involvement (yes vs no).
[a] A g-estimation procedure is used to find the value of the acceleration factor and its 95% CI such that the counterfactual overall survival times are balanced across the treatment groups. Re-censoring is applied to the counterfactual overall survival times.
[b] Hazard ratios are estimated using a stratified Cox proportional hazard model. 95% CIs are estimated using bootstrapping (1000 samples) for RPSFTM and TSE and robust variance estimation for IPCW. **For two-stage approach, accelerated failure time model did not converge for the one bootstrap sample.**
[c] To estimate the acceleration factor, a Weibull accelerated failure time model is fit to the overall survival data of docetaxel patients from the secondary baseline onwards.
The secondary baseline date is the date of the first PD by investigator subsequently confirmed by independent central confirmation of progression. ~~57~~ **56** docetaxel patients are included in the Weibull model fitting based on their available secondary baseline. Of these patients, 45 crossed over to receive sotorasib.
Source: Modified from Table 14-4.1.501 of CodeBreaK 200 Primary Analysis