

## Davidson, Mark

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**From:** Davidson, Mark  
**Sent:** Thursday, April 02, 2015 5:23 PM  
**To:** 'Pernice, Michelle'  
**Subject:** RE: BLA 125518. IR regarding durable CRs

Dear Michelle,

Please see the following request for information (RI) regarding durable responders. Please provide a response as soon as available.

1. Please provide the information for EAC-determined durable complete responders:
  - a. Please provide a table (with subjects' ID numbers) for EAC-determined durable complete responders.
  - b. How many of the EAC- durable complete responders remained in complete response at the data cutoff for primary analysis of the primary endpoint or last known tumor response?
  - c. What was the median duration of response (months) for the EAC-determined durable complete responders?
2. Regarding your BLA submission:
  - a. Please provide any information you may have regarding the expected survivals vs. actual survivals of the subjects by stage and by treatment arm.
3. Regarding your AC briefing document:
  - a. You report in Section 4.1.3.2 Table 13 of your BD an analysis of Clinical outcomes – cosmetic benefit – please provide the USID numbers of the subjects who obtained cosmetic benefit and the basis for this assessment and whether you have submitted this information into the BLA.
  - b. You report in Section 4.1.3.3 Figure 14 of your BD an analysis of Noninjected Visceral Lesions – please clarify if these lesions were ever injected.
  - c. Regarding the OS subgroups, if you have any analyses using updated information regarding the survival of subgroups or analyses of the combined stage III and M1a subgroups please provide these analyses.
  - d. You report under Systemic Effects an analysis of Risk of Developing Visceral Metastases. Please provide information on the source datasets along with the method for analysis from which you obtained the results (hazard ratio = 0.41, 95% CI: 0.19, 0.89; descriptive p = 0.024).
  - e. Since your proposed indication does not include the term 'unresectable,' but this was part of the eligibility criteria, please confirm the number and % of subjects on each arm who did not have unresectable melanoma at screening.

Best

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