**BLA 125643 Clinical information request, 4/24/2017**

**Response due 2 pm EST, Wednesday April 26, 2017**

1. Response by central review (ZUMA1): In response to IR part A received 4/21/17, you stated that 3 patients in the mITT population had response evaluated by investigator but not by central review:

| Subject | Investigator Assessment | Central Assessment | Comment |
|---|---|---|---|
| 101-002-007 | Y | N | (b) (4) internal edit checks identified a discrepancy unrelated to the data content that precluded transfer prior to the data cutoff. |
| 101-002-021 | Y | N | Clinical data were not yet available at the time of the database snapshot for (b) (4) to complete the oncology assessment. |
| 101-019-001 | Y | N | Clinical data were not yet available at the time of the database snapshot for (b) (4) to complete the oncology assessment. |

   However:
   - Patient 101-002-007 from this list, despite no central assessments in ADRS.xpt, ADEFF.xpt, and ADTTE.xpt, has a CR by central review in ADSL.xpt (variable "BESTRSOC").
   - Patient 101-019-001 from this list has a CR by central review (for example, in ADEFF.xpt, ADRS.xpt, ADSL.xpt).
   - Patient 101-019-009, not on this list, has CR by investigator assessment but no central assessments in ADSL.xpt , ADEFF.xpt, ADTTE.xpt (apart from PFS), and ADRS.xpt.

   For review of efficacy,
      a. Resolve these inconsistencies.
      b. Clarify in each case which results were used in your reported efficacy analyses.
      c. Submit revised .xpt datasets for any datasets with incorrect entries.

2. ADTR.xpt (ZUMA1):
      a. For the post-baseline  parameter of "Target Lesion Tumor Burden,"  measures at multiple time points are provided. To identify the maximal tumor reduction for a waterfall plot, please confirm  one would select the lowest value in the variable "PCHG" (% change), or describe the method.
      b. For the  parameter "Target Lesion Tumor Burden",  99 patients in the mITT population (period 1) had a baseline value.  Clarify why only 98 have a post-baseline value.