

## Davidson, Mark

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**From:** Davidson, Mark  
**Sent:** Friday, June 02, 2017 12:26 PM  
**To:** Rizwana Sproule  
**Cc:** 'Nadia Agopyan'; Alex Babayan  
**Subject:** BLA 125643 Biostatistical IR June 2, 2017

**Importance:** High

Dear Dr. Sproule,

We have the following statistical request for information:

In study ZUMA1, the subject KTE-C19-101-006-002 had a best overall response of CR per investigator which was assessed on 29DEC2016. However, this subject had ASCT on 25OCT2016, which was prior to the investigator's CR assessment. Per protocol, ORR includes only response assessments after KTE-C19 infusion and prior to any other additional therapy including SCT. Prior to ASCT, this subject had the best overall assessment of PR. Please clarify why this subject had CR for the primary endpoint ORR.

**Please respond by June 5, 2017.**

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