KITE BLA 125643 - Clinical IRs 5/17/2017.
Response due COB Monday 5/22/2017.

1. Per the SAP and October 2016 pre-BLA meeting, all ZUMA1 patients in the primary efficacy cohort (N=92; inference test population flag of "Yes") must have been followed for efficacy for at least 6 months after KTE-C19 infusion. Nearly all survivors in this cohort were followed for 6 months for OS. However, we note that of the 41 patients without PFS events per investigator,
   – 30% were followed for < 6 months for PFS.
   – two-thirds had < 6 month follow up for DOR, as shown below.

For review of efficacy and data adequacy, describe how these data fulfill the requirements set forth at the pre-BLA meeting regarding minimum duration of follow up.

USUBJID	AVAL DOR_invest	CNSR DOR_invest	AVAL PFS_invest	CNSR PFS_invest
KTE-C19-101-014-003	•	•	5.59	1
KTE-C19-101-009-010	0.03	•	6.05	1
KTE-C19-101-002-015	0.03	•	6.05	1
KTE-C19-101-007-001	1.77	•	2.73	1
KTE-C19-101-024-002	2.10	•	4.90	1
KTE-C19-101-015-006	2.33	•	5.91	1
KTE-C19-101-012-002	2.50	•	3.45	1
KTE-C19-101-014-002	2.89	•	5.91	1
KTE-C19-101-002-020	3.02	•	5.88	1
KTE-C19-101-005-004	3.68	•	6.31	1
KTE-C19-101-006-002	4.24	•	7.00	1
KTE-C19-101-019-007	4.40	•	5.82	1
KTE-C19-101-025-006	4.67	•	5.62	1
KTE-C19-101-024-004	4.83	•	5.72	1
KTE-C19-101-001-005	4.90	•	5.85	1
KTE-C19-101-003-018	4.90	•	5.85	1
KTE-C19-101-015-005	5.03	•	5.98	1
KTE-C19-101-003-024	5.06	•	6.01	1
KTE-C19-101-002-019	5.09	•	6.11	1
KTE-C19-101-003-025	5.13	•	6.08	1
KTE-C19-101-003-014	5.13	•	6.08	1
KTE-C19-101-009-012	5.32	•	6.24	1
KTE-C19-101-019-008	5.32	•	6.28	1
KTE-C19-101-002-018	5.36	•	6.21	1
KTE-C19-101-020-001	5.36	•	6.31	1
KTE-C19-101-024-001	5.68	•	8.34	1
KTE-C19-101-015-003	5.68	•	8.64	1
KTE-C19-101-005-002	5.72	•	8.84	1

2. For efficacy review, clarify why the median DOR is 2.7 months longer per investigator assessment (8.1 months) than per IRC (5.4 months).

3. For ZUMA1, please clarify which analysis dataset and variable indicate the date of delivery of KTE-C19 to the study site, as opposed to the date of infusion.

4. For labeling review, submit a revised word file of the draft PI that has section headings and subheadings formatted as such, to enable navigation of the document in the navigation page.

5. The trans-z1.xpt file (listing of ZUMA1 patients with subsequent SCT) was submitted with SCHOLAR1 datasets instead of ZUMA1 datasets. For navigability of the BLA submission, resubmit the file under SCHOLAR1.