

Davidson, Mark

From: Davidson, Mark
Sent: Thursday, May 25, 2017 3:25 PM
To: Rizwana Sproule (RSproule@KitePharma.com)
Cc: Nadia Agopyan (NAgopyan@KitePharma.com); 'Alex Babayan'
Subject: KITE BLA 125643 Data Information Request - May 25, 2017

Importance: High

Hi Dr. Sproule,

You have not provided sufficient follow-up to characterize the duration of response (DOR) in ZUMA1. Per the minutes from the October 31, 2016 pre-BLA meeting, "The totality of data, including the ORR, CR, and duration of complete response after completion of six month follow-up for all subjects, is necessary to assess the efficacy of your product." There is a large amount of censoring in particular for DOR prior to 6 months.

To inform efficacy, updated efficacy data according to investigator and IRC are necessary for the ZUMA1 phase 2 mITT population (N = 101). By June 30, 2017, submit updated efficacy datasets with a data cutoff of late May 2017 for all patients, with efficacy determined both by investigator and by IRC using the same data cutoff date.

At minimum, the datasets are to include best overall response, duration of response with associated censor, and PFS with associated censor, with and without censoring for SCT. Submit analysis (ADAM) .xpt files, raw (SDTM) .xpt files, and associated define files.

Please respond by June 30, 2017.

Thank You

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