

Davidson, Mark

From: Davidson, Mark
Sent: Friday, July 07, 2017 11:52 AM
To: 'Rizwana Sproule'
Cc: 'Nadia Agopyan'; 'Alex Babayan'
Subject: Kite Pharma BLA 125643 Clinical Information request July 7, 2017

Importance: High

Dear Dr. Sproule,

Reference is made to the 7/5/2017 information request to provide PFS sensitivity analysis data in ADTTE.xpt. You responded that "this sensitivity analysis was felt to be of limited value and was not reported." To reiterate, for the efficacy review, submit a revised ADTTE.xpt is that contains both the DOR sensitivity analysis and PFS sensitivity analysis, each per investigator and IRC, in which censoring occurs at the time of ASCT. Note, per the 7/6/2017 statistical information request, that censoring for DOR (as with PFS) is to occur at the time of ASCT, not last disease assessment prior to ASCT.

Submit the revised data by 12 pm EST, Monday July 10, 2017.

Thank You

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