

Davidson, Mark

From: Davidson, Mark
Sent: Monday, August 14, 2017 11:18 AM
To: 'Rizwana Sproule'
Cc: 'Alex Babayan'; 'Nadia Agopyan'
Subject: Kite Pharm 125643 PMR IR 8.14.17

Importance: High

Dear Dr. Sproule,

Your pharmacovigilance plan for Yescarta proposes a postmarketing registry study to evaluate specific safety concerns, including risk of secondary malignancy. Please provide a study concept or protocol for the proposed registry. Please include the following information for the postmarketing study proposal: *study design, sample size and statistical analysis plan, information to be collected at baseline, frequency and methods for follow-up data collection, information to be collected in follow-up, duration of follow-up, study timeline and milestone dates.*

Please provide your response on or before August 18, 2017.

Thank You

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