

Davidson, Mark

From: Davidson, Mark
Sent: Tuesday, August 08, 2017 11:52 AM
To: 'Rizwana Sproule'
Cc: 'Alex Babayan'; 'Nadia Agopyan'
Subject: Kite BLA 125643 Clinical IR August 8, 2017

Importance: High

Hi Dr. Sproule,

In response to our Information Request June 20, 2017, you provided an analysis of the activity of tocilizumab in your response document submitted July 12, 2017. End-of-text Table 1.5 in your response document is a shift table from grade of CRS on day of first tocilizumab infusion to grade of CRS 2 days after first tocilizumab infusion. The data files submitted July 18, 2017, included the dates of tocilizumab infusions, the worst grade of CRS, and the CRS grade 2 days after first tocilizumab dose, but we were not able to identify the variable with the grade of CRS on the day of first dose of tocilizumab. Please identify the variable. If it was not included in the data file, please submit a corrected file with the variable denoting grade of CRS on the day of first dose of tocilizumab.

Please respond by August 11, 2017.

Thank You

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