

Davidson, Mark

From: Davidson, Mark
Sent: Wednesday, October 11, 2017 2:54 PM
To: 'Rizwana Sproule (RSproule@KitePharma.com)'
Cc: 'Alex Babayan'; 'Nadia Agopyan (NAgopyan@KitePharma.com)'
Subject: Kite Pharma 125643 PMR IR 10.11.17

Importance: High

Hi Dr. Sproule,

We have reviewed the draft protocol for the post-marketing study that was submitted October 3, 2017, and note several additional revisions that must be addressed before the protocol can be accepted as final:

- 1) We note that the stated primary objective of the study is to evaluate the development of secondary hematological malignancies following administration of axicabtagene ciloleucel. Revise this objective to remove the qualifier "hematologic" such that all secondary tumors are evaluated, including solid tumors. Accordingly, modify the stated primary endpoint to reflect that all secondary malignancies will be assessed. In addition, amend the sample collection plan to reflect that biospecimen collection and analysis will be performed for all secondary malignancies, including solid tumors.
- 2) We note that you are planning to enroll 1500 patients in your PMR study, of which 500 will be from the ongoing ZUMA studies. While this is acceptable, please confirm that these 500 patients will remain in the long term follow-up studies under the IND in addition to the PMR registry study and will be representative of the patient population treated under this BLA.
- 3) Amend the protocol to reflect an enrollment eligibility period of one week prior or up to 3 months (not 6 months) after receiving axicabtagene ciloleucel infusion.
- 4) As you proposed, the secondary endpoints will include rates and severity of CRS and neurologic toxicities. Revise your protocol to include the following other endpoints as secondary endpoints: rate of relapse of primary malignancy and rate and severity of adverse events of special interest, including serious infections, prolonged cytopenias, hypogammaglobulinemia, and pregnancy outcomes in females of childbearing potential treated with axicabtagene ciloleucel.

Please acknowledge PMR agreement to Item 1 via email by COB October 12, 2017. The remainder of these PMR amendments can be addressed in the final protocol.

Thank You

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