Our STN: BL 125703/0

MID-CYCLE COMMUNICATION AGENDA
MARCH 24, 2020

Kite Pharma Inc.
Attention: Sophia Siu
2400 Broadway
Santa Monica, CA 90404

Dear Ms. Siu:

Attached is a copy of the agenda for your March 26, 2020 Mid-Cycle Communication Teleconference with CBER.

Please include a reference to STN 125703/0 in your future submissions related to the subject product.

If you have any questions, please contact at (240) 772-6272.

Sincerely,

Crystal Melendez, MT, RN BSN
Regulatory Project Manager
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Mid-Cycle Communication Teleconference Agenda

Application type and number: BLA 125703/0
Product name: KTE-X19; autologous chimeric antigen receptor (CAR) T cell product
Proposed Indication: For the treatment of adult patients with relapsed/refractory mantle cell lymphoma (r/r MCL)
Applicant: Kite Pharma Inc.
Meeting date & time: March 26, 2020 at 15:00-16:00 pm
Committee Chair: Graeme Price, PhD
RPM: Crystal Melendez MT, RN, BSN and Adriane Fisher MPH, MBA

FDA Attendees:
Meghna Alimchandani, MD, CBER/OBE
Adriane Fisher, MPH, MBA CBER/OTAT/DRPM
Denise Gavin, PhD, CBER/OTAT/DCGT
Christopher Jason, MD CBER/OBE/DE/PB
Adamma Mba-Jonas, MD, MPH CBER/OBE/DE/PB
Crystal Melendez, MT, RN, BSN CBER/OTAT/DRPM
Graeme Price, PhD, CBER/OTAT/DCGT/GTIB

Kite Pharma, Inc. Attendees:
TBD

Agenda:

The Mid Cycle Meeting will primarily consist of Discipline review updates including any issues of concern that warrant a discussion.

Discussion Summary:

1. Any significant issues/major deficiencies, categorized by discipline, identified by the Review Committee to date.

   CMC: Please provide an update regarding the status of the non-proprietary (USAN) name.

   There are no significant issues/major deficiencies identified at this time in all other disciplines.

2. Information regarding major safety concerns.

   There are no major safety concerns identified at this time.

3. Preliminary Review Committee thinking regarding risk management.

We have determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of KTE-X19 outweigh the risks of Cytokine Release Syndrome and Neurotoxicity. We are reviewing the proposed combined REMS program for KTE-X19 and Yescarta and will be in communication with you regarding the details of the REMS program at a later date.

The pharmacovigilance plan for KTE-X19 includes a long-term follow-up registry of KTE-X19 recipients; the preliminary protocol is currently under review.

4. Any information requests sent, and responses not received.

   Not at this time

5. Any new information requests to be communicated.

   CMC: Please provide 12-month stability updates for KTE-X19 PPQ lots when this data is available.

6. Proposed date for the Late-Cycle meeting (LCM).

   a. The LCM between you and the Review Committee is currently scheduled for May 28, 2020 3-4:30pm EST.

   b. We intend to send the LCM meeting materials to you approximately 10 days in advance of the LCM.

   c. If these timelines change, we will communicate updates to you during the course of the review.

7. Updates regarding plans for the AC meeting.

   There are no plans for an AC meeting at this time.

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.

   There are no changes at this time.

End