Our STN: BL 125703/0

LATE-CYCLE MEETING MEMORANDUM

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

Dear Ms. Siu:

Attached is a copy of the memorandum summarizing your May 28, 2020 Late-Cycle Meeting by teleconference with CBER. This memorandum constitutes the official record of the teleconference meeting. If your understanding of the teleconference meeting outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER in writing as soon as possible.

Please include a reference to the appropriate Submission Tracking Number (STN) in future submissions related to the subject product.

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

Sincerely,

Raj K. Puri, MD, PhD
Director
Division of Cellular and Gene Therapies
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Late-Cycle Meeting Summary

Meeting Date and Time: May 28, 2020 3-4:30PM EST
Meeting Location: WebEx Teleconference
Application Number: 125703/0
Product Name: KTE-X19; autologous chimeric antigen receptor (CAR) T cell product
P**roposed Indication:** For the treatment of adult patients with relapsed/refractory mantle cell lymphoma (r/r MCL)
Applicant Name: Kite Pharma Inc.
Meeting Chair: Graeme Price, PhD
Meeting Recorder: Crystal Melendez MT, RN BSN and Adriane Fisher MPH, MBA

FDA ATTENDEES
Kimberly Benton, PhD, CBER/OTAT
Nannette Cagungun, MS, PD, RAC, CBER/OTAT/DRPM
Eden Chane, MS, CBER/OTAT/DRPM
Adriane Fisher, MPH, MBA CBER/OTAT/DRPM
Denise Gavin, PhD, CBER/OTAT/DCGT
Bindu George, MD, CBER/OTAT/DCEPT
Christopher Jason, MD CBER/OBE/DE/PB
Dana Jones CBER/OCBQ/APLB
Bhanu Kannan CBER/OCBQ/DIS/BMB
Carolyn Laurencot, PhD, CBER/OTAT/DCGT
Sarah Lee, CBER/OCBQ/DMPQ
Adamma Mba-Jonas, MD, MPH CBER/OBE/DE/PB
Crystal Melendez, MT, BSN, RN CBER/OTAT/DRPM
Margret Merino, MD CDER/OCE
Narayan Nair, CBER/OBE/DE
Steven Oh, PhD, CBER/OTAT/DCGT
Helkha Peredo-Pinto, MD CBER/OTAT/DCEPT
Lori Peters, CBER/OCBQ/DMPQ
Graeme Price, PhD, CBER/OTAT/DCGT/GTIB
Raj Puri, MD, PhD, CBER/OTAT/DCGT
Ramani Sista, PhD, CBER/OTAT/DRPM
Lisa Stockbridge, PhD, CBER/OCBQ/DCM/APLB
Marc Theoret, MD, OCE
Neil Vora, CDER/OSE/PMS
Xiaofei Wang, PhD, CBER/OTAT/DCEPT
Megan Zimmerman, MD, CBER/OTAT/DCEPT
Tejashri Purohit-Sheth, MD, CBER/OTAT/DCEPT

APPLICANT ATTENDEES
Aliya Omer, MBA
Anne Kerber, MD
Mehrshid Alai-Safar, PhD
Erik Poulsen
Swami Murugappan, MD, PhD
Kanti Thirumoorthy, PhD
Bita Badiei, RAC
Chuck Smith, MD, PhD
John Rossi, MS
Bryan Silvey
Paul Wang, PharmD
Alison Blaus, RAC
Ellie Huang
Weimin Peng, PhD
Jo-Ann Peterson, PharmD
Sophia Siu, MS

BACKGROUND

BLA 125703/0 was submitted on December 11, 2019, for brexucabtagene autoleucel.

Proposed indication: For the treatment of adult patients with relapsed/refractory mantle cell lymphoma (r/r MCL)

PDUFA goal date: August 10, 2020

In preparation for this meeting, FDA issued the Late-Cycle Meeting Materials on May 19, 2020.

DISCUSSION

1. Discussion of Substantive Review Issues

   CMC
   As discussed at the mid-cycle meeting, please provide 12-month stability data from the KTE-X19 PPQ lots when this information becomes available. To allow sufficient time for review, please provide this data before June 10, 2020 (received, review ongoing). Please note that this updated stability information will be used in our assessment to determine product shelf-life.

   Summary of discussion:
   FDA noted that 12 month PPQ stability data has been received and is under review.

   BIMO inspections
   Inspections are ongoing. A final recommendation is pending at this time. However, if we learn of any issues from the outstanding facility inspections, the agenda will be modified accordingly.

   Summary of discussion:
   FDA clarified that this refers to clinical site inspections. No GMP inspections of manufacturing sites will be performed due to a satisfactory recent inspectional history.

2. Discussion of Minor Review Issues
   There are no minor review issues at this time.

3. Additional Applicant Data
   IR#26 and IR#28 already submitted

4. Information Requests
   a. IR#28- CMC Labeling for Bag and cassette, received by FDA
   b. Combined REMS - FDA review is ongoing for the proposed combined REMS program for KTE-X19 and Yescarta, and FDA will be in communication with the applicant regarding the details of the REMS program.
   c. IR#26- Clinical Datasets, received by FDA and review is ongoing

5. Discussion of Upcoming Advisory Committee Meeting
   An Advisory Committee meeting is not planned.

6. Risk Management Actions (e.g., REMS)
   RISK MANAGEMENT/REMS ACTIONS HAVE BEEN IDENTIFIED
   Combined REMS -- FDA review is ongoing for the proposed combined REMS program for KTE-X19 and Yescarta, and FDA will be in communication with the applicant regarding the details of the REMS program.

7. Postmarketing Requirements/Postmarketing Commitments

   PMR long-term follow-up for malignancy -- Should this product be approved, FDA has determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) and the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA will not be sufficient to identify a serious risk of secondary malignancies associated with use of KTE-X19. Therefore, should this product be approved, based on appropriate scientific data, FDA has determined that the proposed prospective, observational, postmarket registry study KT-US-472-5655, will be a postmarketing requirement (PMR) under Section 505(o) of FDCA, to assess the long-term safety of KTE-X19 and the risk of secondary malignancies occurring after treatment with KTE-X19. The study will include at least 500 patients with relapsed/refractory (R/R) Mantle Cell Lymphoma and enrolled patients will be followed for 15 years after product administration.

8. Major Labeling Issues

   There are no major issues identified at this time.

9. Review Plans

   Review of the BLA is ongoing.

10. Applicant Questions

    Inspections: Discussion about manufacturing/clinical sites:
    The applicant inquired about the possibility of a BIMO inspection of the sponsor site. BIMO responded that there is no plan to inspect the applicant site at this time.

    Combined REMS: Is a combined REMS appropriate? A combined REMS for Yescarta and KTE X19 is appropriate. The REMS program materials submitted by the applicant are under review.

    Proposed Indication: The indication statement is under discussion and will be communicated via labelling revisions that will be communicated to the Applicant.

    Confirmatory Post-Marketing Required Study subject to a decision on Accelerated vs Regular approval: At this time a final decision as to the type of approval if an approval is planned has not been determined. In general, for products under development under the accelerated approval pathway, confirmatory trials are well underway at the time of submission of a marketing application. If the Agency decides that an approval under accelerated approval is planned, the Agency will work with the applicant in finalizing the design of a confirmatory study prior to approval.

11. Wrap-up and Action Items

None

This application has not yet been fully reviewed by the signatory authorities, Division Directors and Review Committee Chair and therefore, this meeting did not address the final regulatory decision for the application.