Memorandum

DATE	July 17, 2020
FROM	Bhanu Kannan, Bioresearch Monitoring Branch Division of Inspections and Surveillance Office of Compliance and Biologics Quality Telephone: 240-402-8979 Fax: 301-595-1304
THROUGH	Dennis Cato, Chief, Bioresearch Monitoring Branch
THROUGH	Carrie Mampilly, M.P.H., Director, Division of Inspections and Surveillance
TO	Graeme Price, Ph.D., Chair, STN 125703/0 Megan Zimmerman, M.D., Clinical Reviewer Helka Peredo-Pinto, M.D., Clinical Reviewer Crystal Melendez, RPM Adrian Fisher, RPM
SUBJECT	Bioresearch Monitoring Final Review Memo
SPONSOR	Kite Pharma, Inc.
PRODUCT	KTE-X19 (Autologous anti-CD19 chimeric antigen receptor (CAR) T-cell product)
BLA	STN 125703/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were conducted at three domestic clinical investigator sites participating in the conduct of study protocol KTE-X19. The inspections did not reveal significant problems impacting the data submitted in support of this Biologics License Application (BLA).

Background

Three clinical investigators (CI) were inspected in support of this BLA. The inspection was conducted in accordance with FDA's Compliance Program (CPGM) 7348.811, Inspection Program for Clinical Investigators. The inspection assignments were issued for the following study protocol:

Protocol KTE-X19-102 (ZUMA 2)- *A Phase 2 Multicenter Study Evaluating the Efficacy of KTE-X19 in Subjects with Relapsed/Refractory Mantle Cell Lymphoma*

The sites were selected based on previous inspectional history, geographic location, and the data submitted in the BLA. The inspection assignment included specific questions concerning the study protocol, and information submitted in the BLA was compared to

source documents at the site. Study KTE-X19-102 was conducted globally at 33 sites, enrolling a total of 91 subjects in two study cohorts. Three domestic CI sites inspected in support of this BLA covered approximately 35% of the subjects enrolled in study KTE-X19-102.

Inspection Outcome

Site ID	Number of subjects randomized	Location	483 Issued	Final Inspection Classification
03	20	MD Anderson Cancer Center, Houston, Texas	No	No Action Indicated
12	6	University of Rochester Medical Center, Rochester, New York	No	No Action Indicated
20	6	Banner MD Anderson Cancer Center, Gilbert, Arizona	No	No Action Indicated

The inspections verified the data reported in the BLA, including but not limited to: subject eligibility, protocol deviations, study drug administration, primary efficacy endpoint, and adverse events for all subjects enrolled at the inspected clinical sites. No Form FDA 483s were issued for three sites that participated in the study.

Noteworthy inspectional findings
None.

Sponsor Issues
No significant sponsor issues were noted.

Financial Disclosure
The Clinical Investigator Compliance Program directs the FDA investigators to ask the clinical investigator if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouses and dependent children, and if and when the information was updated. The information submitted to the BLA was verified at the inspected clinical sites no deviations were found in the submitted data.

Administrative follow-up

No administrative follow-up is warranted at this time from BIMO for the inspected clinical investigators. Should you have any questions about the contents of this memo or any aspect of BIMO, please contact me at 240-402-8979.

Bhanu Kannan, M.S.
Consumer Safety Officer

Electronic Copies
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History:
Kannan draft: 07/17/2020