



**U.S. FOOD & DRUG
ADMINISTRATION**

DATE September 30, 2020

FROM Christine Drabick, Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH Dennis Cato, Branch Chief, Bioresearch Monitoring Branch

THROUGH Carrie Mampilly, Director, Division of Inspections and Surveillance

TO Kimberly Schultz, Ph.D., Chair, BLA STN 125714/0
Kavita Natrajam, M.D., Clinical Reviewer
Zakaria Ganiyu, M.S., RPM

SUBJECT Bioresearch Monitoring Final Discipline Review Memo

SPONSOR: Juno Therapeutics

PRODUCT: lisocabtagene maraleucel (BREYANZI)

BLA : STN: 125714/0

FINAL SUMMARY STATEMENT:

Bioresearch Monitoring (BIMO) inspections were issued for four clinical sites participating in the conduct of study protocol 017001. Three of the four issued inspections were completed and did not reveal substantive problems impacting the data submitted in the application. The fourth inspection was cancelled due to COVID-19 and competing priorities.

BACKGROUND:

Four BIMO clinical investigator inspection assignments were issued in support of this Biologics License Application. The clinical sites were selected based on subject enrollment, previous inspectional history, the data submitted in the BLA, and other factors.

Fourteen United States sites enrolled subjects. 268 subjects received at least one dose of the study product. The three inspected sites represented 54% of the enrolled subjects.

The inspections were conducted in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for Clinical Investigators. Information submitted in the BLA was compared to source documents at the sites. The inspection assignments included specific questions concerning the clinical study.

PROTOCOL: The conduct of the following protocol was evaluated:

A Phase 1, Multicenter, Open-label Study of JCAR017, CD19-targeted Chimeric Antigen Receptor (CAR) T Cells, for Relapsed and Refractory (R/R) B-cell Non-Hodgkin Lymphoma (NHL) (Protocol 017001)

BIMO INSPECTION SUMMARY:

Four BIMO inspection assignments were issued for this BLA. Three of the inspections were completed and classified as No Action Indicated (NAI). One inspection was cancelled due to COVID-19.

Site ID	Establishment for Inspection	FDA Form 483 Issued?	Inspection Status
0002	MD Anderson Cancer Center Houston, Texas 77030		Cancelled
0005	Massachusetts General Hospital Boston, Massachusetts 02114	No	No Action Indicated (NAI)
0007	City of Hope Duarte, California 91010	No	No Action Indicated (NAI)
0020	University of Colorado Cancer Center Aurora, Colorado 80045	No	No Action Indicated (NAI)

SIGNIFICANT INSPECTIONAL FINDINGS:

No significant inspectional findings were observed.

SPONSOR ISSUES:

No sponsor issues were identified.

FINANCIAL DISCLOSURE:

The Clinical Investigator Compliance Program directs the FDA investigator 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, spouse(s) and dependent children, and if and when the information was updated. The information submitted to the BLA was verified for each of the inspected clinical sites.

ADMINISTRATIVE FOLLOW-UP:

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 240-402-8928.

Christine J. Drabick, MS
Consumer Safety Officer