U.S. FOOD & DRUG ADMINISTRATION

DATE: February 18, 2021

FROM: Anthony Hawkins, M.S., Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH: Dennis Cato, Chief, Bioresearch Monitoring Branch

THROUGH: Carrie M. Mampilly, M.P.H., Director, Division of Inspections and Surveillance

TO: Anna Kwilas, Ph.D., BLA Chair
Poornima Sharma, M.D., BLA Clinical Reviewer
Colleen Caldwell, BLA RPM
Juliane Carvalho, BLA RPM

SUBJECT: Bioresearch Monitoring Final Discipline Review

SPONSOR: Celgene Corporation, a Bristol-Myers Squibb Company
PRODUCT: idecabtagene vicleucel
BLA: STN 125736/0

FINAL SUMMARY STATEMENT:
Bioresearch Monitoring (BIMO) inspections were issued for four U.S. clinical investigators who participated in the conduct of protocol BB2121-MM-001. The inspections did not reveal substantive issues that impact the data submitted in this Biologics License Application supplement (BLA).

BACKGROUND
Four U.S. clinical study sites under phase 2 protocol BB2121-MM-001 were identified for BIMO inspections. The BLA review committee concurred with the proposed sites. The sites were selected based upon sponsor-reported adverse events, deaths, protocol deviations, total number of enrolled subjects and previous BIMO inspection histories, along with BLA clinical review team recommendations including clinical investigator financial disclosures.

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 each inspected site. The inspection assignment also included specific questions concerning the clinical study.

PROTOCOL:
BB2121-MM-001: *A Phase 2, Multicenter Study to Determine the Efficacy and Safety of BB2121 in Subjects with Relapsed and Refractory Multiple Myeloma*

BIMO INSPECTIONS SUMMARY:
No significant BIMO inspectional findings were noted. The below table summarizes site information and outcomes from the BIMO inspections:

| Site ID | Location | Final Inspection Classification |
|---|---|---|
| Site 102 | Hackensack, New Jersey | No Action Indicated (NAI) |
| Site 104 | Dallas, Texas | No Action Indicated (NAI) |
| Site 108 | San Francisco, California | No Action Indicated (NAI) |
| Site 109 | New York, New York | No Action Indicated (NAI) |

SPONSOR/MONITORING ISSUES
No significant sponsor or monitoring issues were identified during the above inspections.

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, as well as if and when the information was updated. The information submitted to the BLA was verified for each of the inspected clinical study 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) 402-8950.

_____
Anthony Hawkins
Consumer Safety Officer