



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: July 29, 2024

TO: Elvira Argus, PhD, BLA Committee Chair
Katherine Barnett, MD, Clinical Reviewer
Tigist Assefa, PharmD, BLA RPM

FROM: Malcolm Nasirah, PharmD, MS, Regulatory Reviewer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Dennis T. Cato, Associate Director for Bioresearch Monitoring (BIMO)

THROUGH: Carrie M. Mampilly, MPH, Director, DIS

SUBJECT: Bioresearch Monitoring Final Discipline Review Memo

PRODUCT: afamitresgene autoleucel

SPONSOR: Adaptimmune LLC
BLA STN: 125789/0

REVIEW SUMMARY

BIMO inspection assignments were issued for the sponsor and four clinical study sites that participated in the conduct of study Protocol No. ADP-0044-002. The inspections did not reveal substantive issues that impact the data submitted in this Biologics License Application (BLA).

BACKGROUND

The Sponsor, three domestic clinical study sites, and one foreign clinical study site conducting the study Protocol No. ADP-004-002 were identified for BIMO inspections. The sites were selected for inspection based upon previous BIMO inspection history, enrollment numbers, review committee concern, sponsor-reported adverse events, and protocol deviations. The inspected sites comprised of approximately 21.3% of the total subjects enrolled in the intent-to-treat (ITT) population.

The inspections were conducted in accordance with FDA's Compliance Programs (CP) 7348.811, Inspection Program for Clinical Investigators (CI) and (CP) 7348.810, Inspection Program for Sponsors, Contract Research Organizations and Monitors. 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 No. ADP-004-002.

PROTOCOL

Protocol ADP-0044-002: A Phase 2 Single Arm Open-Label Clinical Trial of ADP-A2M4 SPEAR™ T cells in subjects with Advanced Synovial Sarcoma or Myxoid/Round Cell Liposarcoma

BIMO INSPECTIONS SUMMARY

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

Study Site #	Firm Name	Location	FDA Form 483 Issued	Inspectional Final Classification
501	Dejka Araujo, MD	Houston, Texas	No	No Action Indicated (NAI)
506	Mihaela Druta, MD	Tampa, Florida	No	NAI
511	Kristen Ganjoo, MD	Stanford, California	Yes	Voluntary Action Indicated (VAI)
523	Sandra Strauss, MD	United Kingdom	No	NAI
Sponsor	Adaptimmune LLC	Philadelphia, Pennsylvania	No	NAI

INSPECTIONAL FINDINGS:

Study Site 511: At the close of this inspection, a one item FDA 483 was issued for: Not conducting the investigation according to the investigational plan. Specifically, the CI failed to have an impartial witness sign a non-English-speaking subjects pre-screening Informed Consent Form (ICF) by using a sub-investigator to translate and sign the ICF. The CI submitted a 483 Response with a Corrective Action and Preventative Action (CAPA) plan to improve the sites consenting process workflow. The submitted CAPA was reviewed and determined to be adequate and acceptable. This inspection received a final classification of VAI.

The inspections of the sponsor and Sites 501, 506, and 523 revealed no significant observations, and a Form FDA 483 was not issued at close of those inspections. All four of these inspections received a final classification of NAI.

SPONSOR/MONITORING ISSUES

No significant sponsor or monitoring issues were identified during the above inspections.

FINANCIAL DISCLOSURE

The CI CP directs the FDA investigator to ask the CI 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 last 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 301-796-6667 or Malcolm.Nasirah@fda.hhs.gov.

Malcolm Nasirah, PharmD
Consumer Safety Officer

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Draft: Nasirah: 7/15/2024, 7/25/2024

Reviewed: Ravenell: Pending

CATO: 7/25/2024
