



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

DATE: September 04, 2024

FROM: Char-Dell K. Edwards BS, MT (ASCP), Consumer Safety Officer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

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

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

TO: Andrew Timmons, PhD, Committee Chair
Najat Bouchkouj, MD, Clinical Reviewer
Danielle Bauman, MPH, RPM

SUBJECT: Bioresearch Monitoring Final Discipline Review
SPONSOR: Autolus Inc.
PRODUCT: AUCATZYL (obecabtagene autoleucel (Obe-cel))
BLA: BLA STN 125813/0

FINAL SUMMARY STATEMENT:

Bioresearch Monitoring (BIMO) inspection assignments were issued for four Clinical Investigator (CI) study sites (two foreign sites and two domestic sites) that participated in the conduct of study protocol AUTO1-AL1. The inspections did not reveal substantive issues that impact the data submitted in this original Biologics License Application (BLA).

BACKGROUND:

Four Clinical Investigator study sites (two foreign sites and two domestic sites) for protocol AUTO1-AL1 were identified for BIMO inspections. The BLA review committee concurred with the proposed sites. The sites were selected based upon sponsor-reported deaths, adverse events, protocol deviations, number of subjects enrolled, and previous BIMO inspection histories.

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

The BIMO inspection assignments were issued to review the conduct of the following clinical study:

Protocol AUTO1-AL1: An open-label, multi-center, Phase Ib/II study evaluating the safety and efficacy of AUTO1, a CAR T cell treatment targeting CD19, in adult patients with relapsed or refractory B-cell acute lymphoblastic leukemia

INSPECTION SUMMARY AND FINDINGS:

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

Site ID	Firm Name and Location	FDA Form 483 Issued	Final Inspection Classification
GB01	Claire Roddie, PhD, FRCPATH, MRCP, MBChB University College London Hospital NHS Foundation Trust 235 Euston Road London, England, United Kingdom, NW1 2BU	No	No Action Indicated (NAI)
GB06	Eleni Tholouli, MD, PhD, FRCPATH, MRCP, MBChB The Manchester University NHS Foundation Trust Manchester Royal Infirmary, Oxford Road Manchester, England, United Kingdom M13 9WL	No	NAI
US17	Paul Shaughnessy, MD TTI-Methodist (Texas Transplant Institute) 8026 Floyed Curl Drive San Antonio, Texas 78229	No	NAI
US11	Karamjeet Sandhu, MD City of Hope National Medical Center 1500 East Duarte Road Duarte, California 91010	No	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, no deviations were found in the submitted data.

ADMINISTRATIVE FOLLOW-UP

Field Management Directive-145 (FMD-145): Release of Establishment Inspection Report (EIR) to the inspected establishments was fulfilled for the two inspected CIs located in England.

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at (240) 402-2859 or Char-Dell.Edwards@fda.hhs.gov.

Char-Dell K. Edwards, BS, MT(ASCP)
Consumer Safety Officer

DISTRIBUTION

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Andrew Timmons, PhD, Committee Chair, BLA STN 125813/0

Najat Bouchkouj, MD, Clinical Reviewer

Danielle Bauman, MPH, RPM

Carrie Mampilly, MPH, Director DIS

Dennis T. Cato, BIMO Associate Director

cberbimonotification@fda.hhs.gov

Chron File

ORABIMOW.Correspondence@fdahhs.gov

FDAinternationalbimo@fda.hhs.gov

Tracy Ball, OBIMO Investigator

Audrey Yarbrough, OBIMO Investigator

Korina Serrano, OBIMO Investigator

Samson O. Oluseye, OBIMO Investigator

Draft: Edwards 8/23/2024

Reviewed: Cato: 9/4/2024

Reviewed: Mampilly: 9/4/2024
