DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Kathleen R. Jones Telephone: 301-796-7950 Industry Information: www.fda.gov/oc/industry	April 22-26 and 29-30, 2024
	FEI NUMBER 3015674982

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Chris Gray, VP and General Manager Stevenage Operations

FIRM NAME	STREET ADDRESS
Autolus Limited (referred to as The Nucleus)	Marshgate
CITY, STATE AND ZIP CODE Stevenage, Hertfordshire SG1 1FR, United Kingdom	TYPE OF ESTABLISHMENT INSPECTED Drug substance and drug product manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. The validation of the (b) (4) used during the (b) (4) manufacture of the AUCATZYL (Obecabtagene autoleucel) drug product is not complete. Therefore, the validation does not ensure (b) (4) assurance. Specifically,
a. (b) (4) have not been completed on (b) (4), which is used to prepare the (b) (4) lentiviral vector and (b) (4), which is used to prepare (b) (4).
b. In the (b) (4), the validation of the (b) (4) (b) (4) demonstrate growth of (b) (4) in every validation run.

2. Critical utilities ((b) (4)) are not adequately validated or routinely monitored to ensure reproducible quality. Specifically, the validation testing of (b) (4) was performed by collecting a (b) (4) from each (b) (4), and routine monitoring is not performed.

3. Disinfectant (b) (4) studies are inadequate to mitigate cross-contamination. Specifically, the disinfectant (b) (4) study does not include data to support the effectiveness against viral contaminants.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE /s/	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Kathleen R. Jones, Lead Inspector, Lead CSO Kula N. Jha, Biological Reviewer Jessica Chery, Senior Biologist Andrew E. Timmons, Senior Biologist	04/30/2024