

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: The file for BLA 125813

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Applicant: Autolus Inc.

Subject: Review of biological methods and associated validations used for AUTO1 LVV, a critical component Obecabtagene autoleucel

Recommendation: Approval

Executive Summary:

AUTO1 LVV is a critical component of Obecabtagene autoleucel. Analytical methods used to quantify residual impurities in AUTO1 LVV preparations during release testing, and the associated method validation reports, were reviewed.

Conclusion:

The analytical methods and their validations were generally found to be adequate for their intended uses. The firm agreed to provide additional support for specificity and accuracy, of the (b) (4) methods, to CBER by June 30, 2025.

Documents Reviewed:

Section 2.3.S Drug Substance (b) (4)], Section 3.2.S Drug Substance [(b) (4)], SOPs submitted in Amendment #32:

- (b) (4)

- (b) (4)

Background:

On November 17, 2023, Autolus Inc. submitted original BLA 125813/0 for Obecabtagene autoleucel (obe-cel), an autologous gene therapy consisting of patient T cells that are modified ex vivo with lentiviral vector particles (AUTO1 LVVs/(b) (4) /Critical Component), which are critical components of the obe-cel drug substance (CD19 CAR-positive T cells).

(b) (4) on behalf of Autolus Inc., performs commercial manufacturing and release testing activities for AUTO1 LVVs. AUTO1 LVVs are produced by (b) (4)

AUTO1 LVVs in the (b) (4)

The DBSQC reviewer reviewed validation of analytical methods to quantify residual impurities in AUTO1 LVV preparations during release testing. The methods were validated using (b) (4) test samples and AUTO1 LVV-specific test samples. Both LVVs are produced using the same manufacturing process and differ only in their (b) (4).

This review covers the analytical methods used to quantify the following process-related impurities:

(b) (4)

(b) (4)

21 pages determined to be not releasable: (b)(4)