BLA 761115/S-036

SUPPLEMENT APPROVAL

Gilead Sciences Inc
Attention: Tanzir Mortuza, PhD
Senior Manager CMC Regulatory
300 the American Road
Morris Plains, NJ 07950

Dear Dr. Mortuza:

Please refer to your Supplemental Biologics License Application (sBLA) dated September 6, 2022, received September 6, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Trodelvy (sacituzumab govitecan-hziy) for injection.

We also refer to our approval letter dated January 5, 2023, which contained the following error: missing information in the provides for language.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain January 5, 2023, the date of the original approval letter.

This Prior Approval sBLA provides for the following:

- Addition of (b) (4) to perform the cell-based binding assay for (b) (4) lot release and stability testing, sacituzumab govitecan drug substance and drug product stability testing; and (b) (4) as an alternate site to release the cell-based binding assay data generated at (b) (4)

- Addition of (b) (4) to perform the cell-based binding and cytotoxicity assays for sacituzumab govitecan drug substance and drug product lot release and stability testing.

APPROVAL

We have completed our review of this sBLA, as amended. This supplement is approved.

This information will be included in your biologics license application file.

If you have any questions, call Anh-Thy Ly, Regulatory Business Process Manager, at (240) 402 - 1001.

Sincerely,

{See appended electronic signature page}

Qing Zhou, Ph.D.
Review Chief
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Qing Zhou

Digitally signed by Qing Zhou
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