



BLA 761115/S-031

## **SUPPLEMENT APPROVAL**

Gilead Sciences Inc.  
Attention: Rose Gerdesmeier, PharmD  
Associate Director, Regulatory Affairs  
199 East Blaine Street  
Seattle, WA 98102

Dear Dr. Gerdesmeier:

Please refer to your supplemental biologics license application (sBLA) dated and received June 30, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Trodelvy (sacituzumab govitecan-hziy) for injection.

This Prior Approval sBLA provides for revisions to Section 2.4 (Preparation and Administration) of the Trodelvy United States Prescribing Information (USPI).

### **APPROVAL & LABELING**

We have completed our review of this sBLA, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at [FDA.gov](https://www.fda.gov)<sup>1</sup>, that is identical to the enclosed labeling (text for the prescribing information and Patient Package Insert) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effectuated” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as

well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

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

Sincerely,

*{See appended electronic signature page}*

Marjorie Shapiro, Ph.D. for  
Kathleen A Clouse, Ph.D.  
Director  
Division of Biotechnology Review and Research I  
Office of Biotechnology Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

### **ENCLOSURE(S):**

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert



Marjorie  
Shapiro

Digitally signed by Marjorie Shapiro

Date: 12/05/2022 04:38:14PM

GUID: 508da6d700026360986b5a21cc1642e3