NDA 205858/S-018

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Nate Schmidt, MS, MBA
Manager, Regulatory Affairs
199 East Blaine Street
Seattle, WA 98102

Dear Mr. Schmidt:

Please refer to your supplemental new drug application (sNDA) dated January 10, 2022, received January 10, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zydelig (idelalisib) tablets.

This Prior Approval sNDA provides for proposed modifications to the approved Risk Evaluation and Mitigation Strategy (REMS) for Zydelig.

We have completed our review of this supplement application. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Zydelig was originally approved on July 23, 2014, and the most recent REMS modification was approved on March 10, 2022. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS consists of eliminating the communication plan from the REMS, and for release from the requirement for the REMS.

In accordance with section 505-1 of the FDCA, we have determined that the following REMS modifications are necessary to minimize burden on the healthcare delivery system of complying with the REMS:

- Removal of the communication plan

We have determined that the communication plan is no longer necessary to ensure the benefits of Zydelig (idelalisib) outweigh its risks because the communication plan has been completed and the most recent assessment demonstrates that the communication plan has met its goal based on knowledge surveys of healthcare providers that demonstrate acceptable understanding of the risks. No further assessments are necessary to assess the current communication plan.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Zydelig (idelalisib).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Stacie Woods, Safety Regulatory Project Manager, at 301-796-4803 or via email at Stacie.woods@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Shan M. Pradhan, M.D.
Associate Director for Safety (acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SHAN PRADHAN
07/06/2022 03:30:17 PM