NDA 022405/S-025

SUPPLEMENT APPROVAL

Genzyme Corporation
Attention: Stephen Canning
Manager, Regulatory Affairs
450 Water Street
Cambridge, MA 02141

Dear Mr. Canning:

Please refer to your supplemental new drug application (sNDA) dated March 27, 2025, received March 27, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Caprelsa (vandetanib) tablets.

This Prior Approval supplemental new drug application provides for proposed modification to the approved Caprelsa (vandetanib) risk evaluation and mitigation strategy (REMS).

We have completed our review of this supplemental application, as amended. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Caprelsa (vandetanib) was originally approved on April 6, 2011, and the most recent REMS modification was approved on June 26, 2025. The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of eliminating the Caprelsa (vandetanib) REMS.

Elements to Assure Safe Use: We have determined that elements to assure safe use are no longer necessary because the REMS has consistently met its goals for the reporting period beginning February 7, 2015, through February 6, 2025. The 13-year assessment knowledge survey results indicated that prescriber respondents, of which a majority of respondents specialized in oncology, were adequately educated about monitoring and managing the risk of QT prolongation. These results are consistent with previous survey waves. Additionally, several clinical decision support tools and educational resources are available to prescribers and healthcare settings to support QT prolongation and TdP monitoring with the use of Caprelsa. Based on the totality of

the evidence, knowledge of the risks and appropriate management of those risks have been incorporated into the standard of care for Caprelsa.

Implementation System: In addition, because the elements to assure safe use requiring that pharmacies, practitioners, or health care settings that dispense the drug be specially certified are no longer necessary, the implementation system is also no longer necessary as an element of the REMS.

Therefore, because the elements to assure safe use and implementation system are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Caprelsa (vandetanib).

Submit revised labeling in accordance with this REMS Modification.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

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

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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 Emily Pak, Safety Regulatory Project Manager, at 301-837-7531, or via email at Emily.Pak@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Shan M. Pradhan, M.D.
Associate Director for Safety
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
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