



NDA 208573/S-018

## SUPPLEMENT APPROVAL

AbbVie, Inc.  
Attention: Raid Ibrahim  
Senior Manager, Regulatory Affairs  
1 N Waukegan Road  
Dept. PA72, Bldg AP30  
North Chicago, IL 60064

Dear Mr. Ibrahim:

Please refer to your supplemental new drug application (sNDA) received December 18, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Venclexta (venetoclax) tablets.

This Prior Approval supplemental new drug application provides for the following:

- Update of the Venclexta US Prescribing Information (USPI) with the outcome of the mouse embryofetal development (EFD) study and the 6-month transgenic mouse carcinogenicity study with venetoclax and M27, a major metabolite of venetoclax.
- Update of Section 6 Adverse Reactions of the USPI with *Study GO28667 (MURANO): an open-label randomized Phase 3 study in patients with CLL who had received at least one prior therapy to assess venetoclax in combination with rituximab (VEN + R) versus bendamustine in combination with rituximab (B + R)* adverse reaction and laboratory abnormality tables' threshold to 10% or more, to align with comments received from the Agency during label discussions for NDA 208573/S-013.
- Updates of minor typos throughout the USPI, including but not limited to:
  - Update the minimum value of duration of follow-up reported in Section 14 Clinical Trials for CLL14 from (b) (4) months.
  - Update to proportion of patients with TP53 mutation for CLL14 from 7% to 10%.

### **APPROVAL & LABELING**

We have completed our review of this application, 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling text for the Prescribing Information and Medication Guide, with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] 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 (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 application, you are exempt from this requirement.

## **REPORTING REQUIREMENTS**

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

---

<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

If you have any questions, call Beatrice Kallungal, Regulatory Project Manager, at (301) 796-9304.

Sincerely,

*{See appended electronic signature page}*

Nicole Gormley, MD  
Director (Acting)  
Division of Hematologic Malignancies II  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

-----  
**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/  
-----

NICOLE J GORMLEY  
05/29/2020 04:33:48 PM