



NDA 208573/S-020
NDA 208573/S-021

**SUPPLEMENT APPROVAL/
FULLFILLMENT OF POSTMARKETING
REQUIREMENT**

AbbVie Inc.
Attention: Allan Bonsol
Associate Director, Regulatory Affairs
1 N. Waukegan Road
Dept. PA72/Bldg. AP30
North Chicago, IL 60064

Dear Mr. Bonsol:

Please refer to your supplemental new drug applications (sNDA) dated May 22, 2020, received May 22, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VENCLEXTA (venetoclax tablets) for oral use.

These Prior Approval supplemental new drug applications provide for traditional approval of the following indication: VENCLEXTA is indicated in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. Approval of these supplements are based upon results from clinical studies M15-656 (VIALE-A) and M16-043 (VIALE-C).

We also refer to your supplemental new drug application, NDA 208573/S-009, approved November 21, 2018, under Title 21 of the Code of Federal Regulation (CFR) section 314.510 Subpart H for Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses.

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.¹ 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*.²

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).

SUBPART H FULFILLED

As noted above, NDA 208573/S-009 was approved under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of these supplements (NDA 208573/S-020 and NDA 208573/S-021) fulfills Postmarketing Requirements 3545-1 and 3545-2 made under 21 CFR 314.510.

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.

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

² 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>.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submissions dated May 7, 2020 and May 22, 2020, containing the final reports for the following postmarketing requirements listed in the November 21, 2018, approval letter for NDA 208573/S-009.

3545-1 Submit the complete final study report and data that verifies and isolates the clinical efficacy and safety from trial M16-043, a randomized, double-blind, placebo-controlled Phase 3 study of venetoclax co-administered with low-dose cytarabine versus low-dose cytarabine in treatment naïve patients with acute myeloid leukemia who are precluded from receiving standard chemotherapy due to age \geq 75 years or comorbidities. The primary endpoint will be overall survival. An interim analysis of overall survival will be performed and included in the interim analysis submission or the final study report.

3545-2 Submit the complete final study report and data that verifies and isolates the clinical efficacy and safety from trial M15-656, a randomized, double-blind, placebo-controlled Phase 3 study of venetoclax in combination with azacitidine versus azacitidine in treatment naïve patients with acute myeloid leukemia who are precluded from receiving standard chemotherapy due to age \geq 75 years or comorbidities. The primary endpoint will be overall survival. Interim analysis of response rates and overall survival will be performed and included in the interim analysis submission or the final study report.

We have reviewed your submissions and conclude that the above requirements are fulfilled.

This completes all of your postmarketing requirements acknowledged in our November 21, 2018, approval letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

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, call Suria Yesmin, Senior Regulatory Project Manager, at 301-348-1725.

Sincerely,

{See appended electronic signature page}

R. Angelo de Claro, MD
Acting Division Director
Division of Hematologic Malignancies I
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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/

ROMEO A DE CLARO
10/16/2020 10:24:57 AM