CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

215358Orig1s000
215358Orig2s000

Trade Name:	**Scemblix tablets, 20mg and 40mg**
Generic or Proper Name:	**(asciminib)**
Sponsor:	Novartis Pharmaceuticals Corp.
Approval Date:	October 29, 2021

Indication:

Original #1 – Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)

Original #2 – Treatment of adult patients with Ph+ CML in CP with the T315I mutation

CENTER FOR DRUG EVALUATION AND RESEARCH

215358Orig1s000

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215358Orig1s000
215358Orig2s000

APPROVAL LETTER

NDA 215358/Original 1

ACCELERATED APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Alexandra Hendzel, PharmD, MPA
Senior Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936

Dear Dr. Hendzel:

Please refer to your new drug application (NDA) dated June 24, 2021, received June 24, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SCEMBLIX® (asciminib) tablets.

This NDA provides for the use of SCEMBLIX® (asciminib) tablets for the following indications which, for administrative purposes, we have designated as follows:

- NDA 215358/Original #1 – Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)

- NDA 215358/Original #2 – Treatment of adult patients with Ph+ CML in CP with the T315I mutation

The subject of this action letter is NDA 215358/Original 1. A separate action letter will be issued for NDA 215358/Original 2.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved under the provisions of accelerated approval regulations (21 CFR 314.500), effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

Marketing of this drug product and related activities must adhere to the substance and procedures of the referenced accelerated approval regulations.

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).[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert) 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 via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on October 12, 2021, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 215358**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for SCEMBLIX® (asciminib) tablets shall be 24 months from the date of manufacture when stored at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).

ADVISORY COMMITTEE

Your application for SCEMBLIX® was not referred to an FDA advisory committee because the application did not raise significant safety or efficacy issues.

ACCELERATED APPROVAL REQUIREMENTS

Products approved under the accelerated approval regulations, 21 CFR 314.510, require further adequate and well-controlled clinical trials to verify and describe clinical benefit. You are required to conduct such clinical trials with due diligence. If postmarketing clinical trials fail to verify clinical benefit or are not conducted with due diligence, we may, following a hearing in accordance with 21 CFR 314.530, withdraw this approval. We remind you of your postmarketing requirement specified in your

[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.

submission dated October 27, 2021. This requirement, along with required completion dates, is listed below.

4161-1 Conduct clinical study CABL001A2301 (ASCEMBL), A Phase 3, Multi-center, Open-label, Randomized Study of Oral ABL001 Versus Bosutinib in Patients With Chronic Myelogenous Leukemia in Chronic Phase (CML-CP), Previously Treated With 2 or More Tyrosine Kinase Inhibitors and provide the interim report with at least 24 months (96 weeks) follow-up of all patients to describe and confirm the clinical benefit of asciminib.

Final Protocol Submission: 08/2020
Interim Report Submission: 06/2022
Trial Completion: 11/2024
Final Report Submission: 07/2025

Submit clinical protocols to your IND 119257 for this product. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each requirement in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial.

Submit final reports to this NDA as a supplemental application. For administrative purposes, all submissions relating to this postmarketing requirement must be clearly designated "**Subpart H Postmarketing Requirement(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.

We are waiving the pediatric study requirement for ages less than 1 year because necessary studies are impossible or highly impracticable. This is because CML is exceptionally rare in children below 1 year of age.

We are deferring submission of your pediatric study for ages ≥1 to <17 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. This required study is listed below.

4161-2 Conduct a clinical trial to determine the appropriate dose of asciminib and to assess safety, tolerability, pharmacokinetics, and pharmacodynamics of asciminib in pediatric patients with Ph+ CML-CP previously treated with one or more tyrosine kinase inhibitors, ages ≥1 to <18 years and provide the core study report with at least 12 months (52 weeks) data for all patients. Include at least 15 patients ≥1 to <12 years old and 15 patients ≥12 to <18 years old.

Final Protocol Submission:	06/2021
Study Completion:	01/2026
Final Report Submission:	10/2026

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocol(s) to your IND 119257, with a cross-reference letter to this NDA. Reports of this required pediatric postmarketing study must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify an unexpected serious risk of increase toxicity when asciminib is administered concomitantly with breast cancer resistance protein and anion transporting polypeptide substrates.

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following studies:

4161-3 Conduct a physiologically based pharmacokinetic study sufficient to evaluate the effect of repeated doses of asciminib on the single dose pharmacokinetics of a breast cancer resistance protein (BCRP) substrate to address the potential for excessive drug toxicity and determine appropriate dosage recommendations when asciminib is administered concomitantly with BCRP substrates. Design and conduct the study in accordance with the FDA Guidances for Industry titled "Clinical Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions" and/or "Physiologically Based Pharmacokinetic Analyses — Format and Content".

The timetable you submitted on October 27, 2021 states that you will conduct this trial according to the following schedule:

Draft Protocol Submission:	12/2021
Final Protocol Submission:	02/2022
Study Completion:	05/2022
Final Report Submission:	07/2022

Submit the datasets with the final report.

4161-4 Conduct a physiologically based pharmacokinetic study sufficient to evaluate the effect of repeated doses of asciminib on the single dose pharmacokinetics of an organic anion transporting polypeptide (OATP1B) substrate to address the potential for excessive drug toxicity and determine appropriate dosage recommendations when asciminib is administered concomitantly with OATP1B1/3 substrates. Design and conduct the assessment in accordance with the FDA Guidances for Industry titled "Clinical Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions" and/or "Physiologically Based Pharmacokinetic Analyses — Format and Content".

The timetable you submitted on October 27, 2021 states that you will conduct this trial according to the following schedule:

Draft Protocol Submission:	12/2021

Final Protocol Submission:	02/2022
Trial Completion:	04/2022
Final Report Submission:	05/2022

Submit the datasets with the final report.

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[4]

Submit clinical protocol(s) to your IND 119257 with a cross-reference letter to this NDA. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final report(s) to your NDA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate: **Required Postmarketing Protocol Under 505(o), Required Postmarketing Final Report Under 505(o), Required Postmarketing Correspondence Under 505(o).**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B of the FDCA, as well as 21 CFR 314.81(b)(2)(vii) requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B and 21 CFR 314.81(b)(2)(vii) to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 314.81(b)(2)(vii). We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA section 505(o)(3)(E)(ii) and could result in enforcement action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4161-5 Conduct a clinical pharmacokinetic study to evaluate the effect of repeat doses of a strong CYP3A and UGT inducer on the single dose (200 mg) pharmacokinetics of asciminib to assess the magnitude of decreased drug exposure and to determine appropriate dosing recommendations. Design

[4] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

and conduct the study in accordance with the FDA Guidance for Industry entitled "Clinical Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions Guidance for Industry"

The timetable you submitted on October 27, 2021, states that you will conduct this study according to the following schedule:

Draft Protocol Submission: 04/2022
Final Protocol Submission: 07/2022
Study Completion: 12/2022
Final Report Submission: 07/2023

Submit the datasets with the final study report.

4161-6 Conduct in vitro studies to evaluate and characterize the effect of different amounts of hydroxypropyl-β-cyclodextrin on the absorption of asciminib. Identify a threshold amount of hydroxypropyl-β-cyclodextrin that may have a clinically meaningful impact on asciminib bioavailability, which may result in a loss of efficacy. Provide appropriate dosing strategies with concomitant use of these oral drug products with asciminib.

The timetable you submitted on October 27, 2021, states that you will conduct this study according to the following schedule:

Draft Protocol Submission: 01/2022
Final Protocol Submission: 03/2022
Study Completion: 05/2022
Final Report Submission: 08/2022

Submit the datasets with the final study report.

A final submitted protocol is one that the FDA has reviewed and commented upon, and you have revised as needed to meet the goal of the study or clinical trial.

Submit clinical protocols to your IND 119257 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be

prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," **or** "**Postmarketing Commitment Correspondence**."

PROMOTIONAL MATERIALS

Under 21 CFR 314.55, you are required to submit, during the application pre-approval review period, all promotional materials, including promotional labeling and advertisements, that you intend to use in the first 120 days following marketing approval (i.e., your launch campaign). If you have not already met this requirement, you must immediately contact the Office of Prescription Drug Promotion (OPDP) at (301) 796-1200. Please ask to speak to a regulatory project manager or the appropriate reviewer to discuss this issue.

As further required by 21 CFR 314.55, submit all promotional materials that you intend to use after the 120 days following marketing approval (i.e., your post-launch materials) at least 30 days before the intended time of initial dissemination of labeling or initial publication of the advertisement. We ask that each submission include a detailed cover letter together with three copies each of the promotional materials, annotated references, and approved Prescribing Information, Medication Guide, and Patient Package Insert (as applicable).

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*.[5]

REPORTING REQUIREMENTS

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

POST APPROVAL FEEDBACK MEETING

New molecular entities and new biologics qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, contact Rachel McMullen, Senior Regulatory Project Manager, at 240-402-4574.

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

Sincerely,

{See appended electronic signature page}

Marc R. Theoret, MD
Supervisory Associate Director (Acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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/

MARC R THEORET
10/29/2021 12:28:21 PM

NDA 215358/Original 2

NDA APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Alexandra Hendzel, PharmD, MPA
Senior Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936

Dear Dr. Hendzel:

Please refer to your new drug application (NDA) dated June 24, 2021, received June 24, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SCEMBLIX® (asciminib) tablets.

This NDA provides for the use of SCEMBLIX® (asciminib) tablets for the following indications which, for administrative purposes, we have designated as follows:

- NDA 215358/Original #1 – Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)

- NDA 215358/Original #2 – Treatment of adult patients with Ph+ CML in CP with the T315I mutation

The subject of this action letter is NDA 215358/Original 2. A separate action letter will be issued for NDA 21535/Original 1.

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 Patient Package Insert) as well as annual reportable

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the container labeling and/or carton and container labeling submitted on October 12, 2021, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 215358**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for SCEMBLIX® (asciminib) tablets shall be 24 months from the date of manufacture when stored at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).

ADVISORY COMMITTEE

Your application for SCEMBLIX® was not referred to an FDA advisory committee because the application did not raise significant safety or efficacy issues.

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.

We are waiving the pediatric study requirement for ages less than 1 year because necessary studies are impossible or highly impracticable. This is because Ph+ CML is exceptionally rare in children below 1 year of age.

[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.

We are deferring submission of your pediatric study for ages ≥1 to <17 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. This required study is listed below.

4161-2 Conduct a clinical trial to determine the appropriate dose of asciminib and to assess safety, tolerability, pharmacokinetics, and pharmacodynamics of asciminib in pediatric patients with Ph+ CML-CP previously treated with one or more tyrosine kinase inhibitors, ages ≥1 to <18 years and provide the core study report with at least 12 months (52 weeks) data for all patients. Include at least 15 patients ≥1 to <12 years old and 15 patients ≥12 to <18 years old.

Final Protocol Submission:	06/2021
Study Completion:	01/2026
Final Report Submission:	10/2026

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocol(s) to your IND 119257, with a cross-reference letter to this NDA. Reports of this required pediatric postmarketing study) must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

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-*

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Electronic Format – Promotional Labeling and Advertising Materials for Human Prescription Drugs.[4]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

REPORTING REQUIREMENTS

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

POST APPROVAL FEEDBACK MEETING

New molecular entities and new biologics qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, contact Rachel McMullen, Senior Regulatory Project Manager, at 240-402-4574.

Sincerely,

{See appended electronic signature page}

Marc R. Theoret, MD
Supervisory Associate Director (Acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

[4]. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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/

MARC R THEORET
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