NDA 208065/S-016

SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING COMMITTMENT

AstraZeneca Pharmaceuticals LP
Attention: Marilyn Kiral, Pharm.D., Ph.D.
Regulatory Affairs Director
Oncology Regulatory Science & Strategy (ORSS), R&D Oncology
200 Orchard Ridge Drive
Gaithersburg, MD 20878

Dear Dr. Kiral:[1]

Please refer to your supplemental new drug application (sNDA) dated December 10, 2019, received December 10, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tagrisso (osimertinib) tablets, 40 mg and 80 mg.

We also refer to our approval letter dated May 23, 2020, which contained the following error: the approved content of labeling was not enclosed with the, "Supplement Approval/Fulfillment of Postmarketing Commitment," letter that was mailed to you via U.S. postal mail.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain May 23, 2020, the date of the original approval letter.

This Prior Approval supplemental new drug application updates the CLINICAL STUDIES section of the package insert to include mature overall survival data from the Study FLAURA (Protocol D5160C00007), for previously untreated EGFR mutation-positive metastatic non-small cell lung cancer, and additional minor formatting revisions throughout the label.

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

[1] 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.

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) 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).

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.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated December 10, 2019, containing the final report for the following post marketing commitment listed in the April 18, 2018, approval letter:

3381-1 Submit the clinical report and datasets for the final analysis of overall survival, as well as updated duration of response data, for Study FLAURA (Protocol D5160C00007), "A Phase III, Double-Blind, Randomized Study to Assess the Efficacy and Safety of AZD9291 versus a Standard of Care

Epidermal Growth Factor Receptor-Tyrosine Kinase Inhibitor as First-Line Treatment in Patients with Epidermal Growth Factor Receptor Mutation Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer," to update the label with mature duration of response and overall survival data.

We have reviewed your submission and conclude that the above commitment was fulfilled.

This completes all of your post marketing commitments acknowledged in our April 18, 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

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 Jana L. Highsmith, Regulatory Health Project Manager, at 301-348-1823 or e-mail at Jana.Highsmith@fda.hhs.gov.

Sincerely,
{See appended electronic signature page}

Harpreet Singh, M.D.
Director
Division of Oncology 2
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling

- o Prescribing Information
- o 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/

B HARPREET SINGH
05/23/2020 12:00:00 AM