DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208716/S-001

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Eli Lilly and Company
Attention: Guy Ruble, PharmD
Director, Global Regulatory Affairs – Oncology, North America
Lilly Research Laboratories
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Ruble:

Please refer to your Supplemental New Drug Application (sNDA) dated February 28, 2018, received February 28, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Verzenio™ (abemaciclib) Tablets, 50 mg, 100 mg, 150 mg, and 200 mg.

This Prior Approval supplemental new drug application proposes changes to Section 12.3 Pharmacokinetics, Drug Interaction Studies.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information), 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 titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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 REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated February 28, 2018, containing the final report(s) for the following postmarketing commitment listed in the September 28, 2017 approval letter.

3254-3	Conduct Physiologically based Pharmacokinetic modeling (PBPK) analysis to evaluate the effect of repeat doses of a moderate CYP3A4 inducer on the single dose pharmacokinetics of abemaciclib and its active metabolites to assess the magnitude of decreased drug exposure and to determine appropriate dosing recommendations. If the results from the PBPK analysis are inconclusive, conduct a pharmacokinetic trial to evaluate the effect of repeat doses of a moderate CYP3A4 inducer on the single dose pharmacokinetics of abemaciclib and its active metabolites to assess the magnitude of decreased drug exposure and to determine appropriate dosing recommendations. Design and conduct the trial in accordance with the FDA Guidance for Industry entitled “Drug Interaction Studies – Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations.” Submit final report and data sets.

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

We remind you that there are postmarketing requirement(s) and postmarketing commitment(s) listed in the September 28, 2017, approval letter that are still open.

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 Janice Kim, Regulatory Project Manager, at 301-796-9628.

Sincerely,

{See appended electronic signature page}

Laleh Amiri-Kordestani, MD
Supervisory Associate Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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/

LALEH AMIRI KORDESTANI
08/17/2018