



NDA 201023/S-019

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENTS**

Sanofi-Aventis U.S. LLC
Attention: Sunil Gupta, MD
Associate Vice President, Global Regulatory Affairs
55 Corporate Dr., Mail Stop 55C-205A
Bridgewater, NJ 08807

Dear Dr. Gupta:

Please refer to your Supplemental New Drug Application (sNDA) dated November 14, 2016, received November 14, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Jevtana[®] (cabazitaxel), Injection, 60 mg/1.5 mL.

This Prior Approval supplemental new drug application provides for revisions to the Dosage and Administration, Adverse Reactions, and Clinical Studies sections of the Full Prescribing Information based on data contained in two final clinical study reports for studies FIRSTANA (EFC 11784) and PROSELICA (EFC 11785). The supplement also proposes to fulfill PMRs 1649-3 and 1649-4 from the June 17, 2010 approval letter.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. 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 package insert and text for the 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 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, 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(s) 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 REQUIREMENTS

We have received your submission dated November 14, 2016, containing the final reports for the following postmarketing requirements listed in the June 17, 2010, approval letter.

- 1649-3:** Conduct a Phase 3 randomized controlled trial in patients with hormone-refractory metastatic prostate cancer comparing 75 mg/m² docetaxel with prednisone with cabazitaxel 25 mg/m² with prednisone and cabazitaxel 20 mg/m² with prednisone as first-line therapy. The primary endpoint should be overall survival to evaluate the incidence of drug-related death as well as efficacy. The trial should be powered to detect a 25% difference in overall survival. The trial will include interim analyses for evaluation of efficacy based on overall survival and safety of the 25 mg/m² with prednisone arm versus the 20 mg/m² with prednisone arm to potentially drop one of the cabazitaxel arms. Submit the protocol for agency review prior to commencing the trial.

- 1649-4:** Conduct a Phase 3 randomized controlled trial in 1222 patients with hormone-refractory metastatic prostate cancer previously treated with docetaxel comparing cabazitaxel 20 mg/m² with prednisone versus cabazitaxel 25 mg/m² with prednisone and powered to preserve 50% of the treatment effect of cabazitaxel 25 mg/m². The study will include interim analyses for evaluation of drug-related deaths and safety as well as overall survival of the cabazitaxel 25 mg/m² with prednisone arm versus the cabazitaxel 20 mg/m² with prednisone arm to potentially discontinue the trial. Submit the protocol for agency review prior to commencing the trial.

We have reviewed your submission and conclude that the above requirements were fulfilled.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our June 17, 2010, letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

You must submit final promotional materials and package insert(s), 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 <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any

new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

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, contact Rajesh Venugopal, Senior Regulatory Project Manager, at (301) 796-4730.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
Deputy 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 and this page is the manifestation of the electronic signature.

/s/

AMNA IBRAHIM
09/14/2017