DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202379/S-009

SUPPLEMENT APPROVAL

Janssen Research & Development, LLC
Attention: Kelly Reid Johnson, MS, RAC
Associate Director, Regulatory Affairs
920 Route 202
Raritan, NJ 08869

Dear Ms. Reid Johnson:

Please refer to your Supplemental New Drug Application (sNDA) dated August 29, 2013, received August 29, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zytiga® (abiraterone acetate) Tablets, 250 mg.

We acknowledge receipt of your amendments dated September 18, 25, and 27, 2013, February 5, and 20, 2014, and March 7, 17, and 20, 2014.

This "Prior Approval" supplemental new drug application provides for the following changes:

- Updating the package insert and patient labeling to include a post-marketing adverse drug reaction of "non-infectious pneumonitis (lung irritation)" in a new section, 6.2 Post Marketing Experience.
- Updating section 13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertility to include recent carcinogenicity study results.
- Minor editorial changes.

In addition, during the review, the Agency proposed revisions to the Full Prescribing Information sections 2.2 (Dosage and Administration, Dose Modification Guidelines in Hepatic Impairment and Hepatotoxicity), 8.6 (Use in Specific Populations, Patients with Hepatic Impairment), and 12.3 (Clinical Pharmacology, Pharmacokinetics) to incorporate data from an additional clinical trial regarding use in patients with hepatic impairment.

We have completed our review of this supplement 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 includes 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.

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

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
Acting Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
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
05/13/2014