DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204384/S-002

SUPPLEMENT APPROVAL

Janssen Research and Development, LLC
Attention: Gary Lewis
Associate Director, Global Regulatory Affairs
920 U.S. Highway 202
P.O. Box 300
Raritan, NJ 08869-0602

Dear Mr. Lewis:

Please refer to your Supplemental New Drug Application (sNDA) dated June 24, 2013, received June 24, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SIRTURO (bedaquiline) tablets, 100 mg.

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

- HIGHLIGHTS OF PRESCRIBING INFORMATION: Addition of a RECENT MAJOR CHANGES Section.

- Indications and Usage Section (1): Addition of a Limitations of Use sub-section, indicating that the safety and efficacy of SIRTURO for the treatment of infections caused by non-tuberculous mycobacteria (NTM) have not been established.

- Medication Guide, What is SIRTURO™ ? Section, "It is not known if SIRTURO™ is safe and effective in" subsection: addition of the following bullet:
  - people who have an infection caused by bacteria other than TB

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 package insert, Medication

Guide), 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).

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 Fariba Izadi, Pharm.D., Regulatory Project Manager, at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Medication Guide

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
08/28/2013