DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204384/S-005

SUPPLEMENT APPROVAL

Janssen Research & Development, LLC
Attention: Michele Dias, MS
Manager, Global Regulatory Affairs
920 Route 202 South
Raritan, NJ 08869

Dear Ms. Dias:

Please refer to your Supplemental New Drug Application (sNDA) dated September 08, 2014, received September 08, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SIRTURO (bedaquiline) 100 mg Tablets.

We acknowledge receipt of your amendments dated November 13, 2014, April 14, and May 06, 2015.

This "Prior Approval" supplemental new drug application provides for revisions to the WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, DRUG INTERACTIONS, CLINICAL PHARMACOLOGY, MICROBIOLOGY, and CLINICAL STUDIES of the package insert. The Medication Guide was revised to be consistent with the changes made to the package insert. In addition, the package insert was revised to be compliant with the Physician Labeling Rule.

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, 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 Health Project Manager at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling
Med 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
05/14/2015