DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022110/S014

SUPPLEMENT APPROVAL
RELEASE FROM REMS REQUIREMENT

Theravance Biopharma R&D, Inc.
Attention: Joel Lintao, RAC
Senior Manager, Regulatory Affairs
901 Gateway Boulevard
South San Francisco, CA 94080

Dear Mr. Lintao:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 21, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VIBATIV (telavancin) for injection, 750 mg.

This prior approval supplemental application provides for proposed modification to the approved REMS and proposes to eliminate the requirement for the approved REMS for VIBATIV. This supplement is in response to our March 22, 2017, REMS Modification Notification letter.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

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.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for VIBATIV (telavancin) was originally approved on September 11, 2009, and the most recent modification was approved on March 23, 2016. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS. In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the following REMS modifications:

- Eliminate the Medication Guide as an element of the REMS
- Eliminate the Communication Plan as an element of the REMS

Therefore, because the Medication Guide as an element of the REMS and the communication plan are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for VIBATIV (telavancin).

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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Joseph Toerner, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

JOSEPH G TOERNER
05/24/2017