DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022110/S-002

SUPPLEMENT APPROVAL

Theravance Inc.
Attention: Rebecca Coleman, PharmD
Vice President, Regulatory Affairs and Quality
901 Gateway Boulevard
South San Francisco, CA 94080

Dear Dr. Coleman:

Please refer to your supplemental New Drug Application (sNDA) dated July 7, 2011, received July 7, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VIBATIV (telavancin) for Injection, 250 mg and 750 mg.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated March 11, 2011.

This "Prior Approval" sNDA provides for modifications to the approved REMS, in response to our REMS modification notification letter dated June 8, 2011.

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

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENT

The REMS for VIBATIV (telavancin) was originally approved on September 11, 2009. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of:

- A revised Dear Health Care Provider (DHCP) letter that emphasizes the importance of performing a serum pregnancy test before initiating treatment with VIBATIV (telavancin) and dispensing a Medication Guide with every prescription regardless of patient's gender and childbearing potential status.

- A revised DHCP dissemination plan to include, at minimum, expansion of the distribution list to include the following organizations: American Hospital Association, Premier, and the Federation of American Hospitals.

Your proposed modified REMS, submitted on July 8, 2011, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on September 11, 2009 (i.e., next assessment due September 31, 2012). There are no changes to the REMS assessment plan described in our September 11, 2009 letter.

We remind you that assessments of an approved REMS must include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

If you currently distribute or plan to distribute an authorized generic product under this NDA, you must submit a complete proposed REMS that relates only to the authorized generic product. Submit a proposed REMS, REMS supporting document, and any required appended documents as a prior approval supplement. Approval of the proposed REMS is required before you may market your authorized generic product.

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 022110 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022110
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022110 REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES: REMS
DHCP Letter

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
07/27/2011