Initial REMS approval: 09/2009
Most recent modification 03/2016

NDA 22110 Vibativ® (telavancin)
Lipoglycopeptide

Theravance Biopharma Antibiotics, Inc.
c/o Theravance Biopharma US, Inc.
901 Gateway Boulevard, South San Francisco, CA 94080
Phone: 650-808-6076

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of the Vibativ REMS is to mitigate the risks of:

- mortality in patients with pre-existing creatinine clearance of ≤50 mL/min being treated for hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) by informing healthcare providers about this risk

- unintended exposure of pregnant women to Vibativ by:
  - informing healthcare providers and patients of the potential risk of fetal developmental toxicity if women are exposed to Vibativ while pregnant
  - informing healthcare providers that a serum pregnancy test should be performed before initiating therapy with Vibativ in females of reproductive potential
  - informing healthcare providers that females of reproductive potential, including those being treated in the outpatient setting, should be counseled about pregnancy prevention and use of effective contraception during Vibativ use

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide must be dispensed with each Vibativ prescription in accordance with 21 CFR 208.24.

B. Communication Plan

Theravance Biopharma Antibiotics, Inc. (Theravance) must implement the following communication plan to healthcare providers likely to prescribe Vibativ. The communication plan must include:

1. Dear Healthcare Provider Letter

Theravance must send a *Dear Healthcare Provider Letter* within 60 calendar days from the date of approval of the most recent REMS modification (March 2016). Email must be the primary method to disseminate the *Dear Healthcare Provider Letter*. If an email is marked as unopened, a second email must be sent within 7 calendar days of the date

the first email was sent. If the second email is marked unopened, the *Dear Healthcare Provider Letter* must be mailed in hard copy, within 7 calendar days of the date the first set of emails that were sent. If a healthcare provider's email address is not available or if the email is undeliverable, the *Dear Healthcare Provider Letter* must be mailed in hard copy within 7 calendar days of the date the first set of emails were sent. A copy or a link to the Prescribing Information and Medication Guide must accompany each *Dear Healthcare Provider Letter.* Theravance must make the *Dear Healthcare Provider Letter* available via a link from the Vibativ website and through Theravance field based sales and medical representatives upon request for 6 months after approval of the REMS modification (March 2016).

The emailing must include healthcare providers who prescribed Vibativ within the previous 12 months before approval of the modification (March 2016) and newly identified healthcare providers who prescribed or are likely to prescribe or dispense Vibativ. This includes healthcare providers who practice in hospitals, infectious disease, emergency medicine, critical care, general surgery, obstetrics and gynecology, family practice and outpatient infusion centers.

The *Dear Healthcare Provider Letter* is part of the REMS and is appended.

C. Timetable for Submission of Assessments

Theravance must submit REMS assessments to the FDA at 18 months, 3 years, and 7 years from the date of the approval of the REMS modification (6/21/2013). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Theravance must submit each assessment so that it will be received by the FDA on or before the due date.

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
03/23/2016