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Attn Dr. Abadie
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Our ref. NH/IV/08-02106
Your ref.
Date 20 October 2008

CONFIDENTIAL VIA COURIER SERVICE

Subject: Withdrawal of Vibativ®, (telavancin), 15 mg/ml, powder for concentrate for solution for infusion - EMEA/H/C/000864//0000

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Astellas Pharma Europe B.V. has taken the decision to withdraw the application for Marketing Authorisation of Vibativ®, (telavancin), 15 mg/ml, powder for concentrate for solution for infusion, which was intended to be used for the treatment of complicated skin and soft tissue infections in adults.

This withdrawal is based on the following reason:

Astellas has taken this decision based on the CHMP's communication that the data provided are not sufficient to allow the Committee to conclude a positive benefit-risk balance for Vibativ for the applied indication at this time. Astellas currently intends to prepare a new marketing authorisation application (MAA) to include new and expanded clinical trial data in patients with Hospital Acquired Pneumonia, not available at the time of the initial application.

The withdrawal has no consequences for the ongoing clinical trials.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

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I agree for this letter to be published on the EMEA website.

Yours sincerely,
Astellas Pharma Europe B.V.

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