Sandwich Laboratories
Pfizer Limited
Sandwich, Kent CT13 9NJ, UK
Telephone: +44 (0)1304 616161
Facsimile: +44(0)1304 656221

Global Research & Development

9 September 2008

Dr Eric Abadie, CHMP Chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Marketing Authorisation Application for EXULETT®, dalbavancin, 500 mg powder for concentrate for solution for infusion – EMEA/H/C/902

Dear Dr Abadie,

I would like to inform you that, at this point of time, Pfizer has taken the decision to withdraw the application for Marketing Authorisation of EXULETT®, dalbavancin, 500 mg powder for concentrate for solution for infusion, which was intended to be used for complicated skin and soft tissue infections in adults when known or suspected to be caused by susceptible Gram positive bacteria.

This withdrawal is based on the company's decision to conduct a second Phase 3 clinical trial of dalbavancin in the treatment of complicated skin and soft tissue infections due to Gram positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA). This study is intended to generate additional clinical data to support planned future regulatory filings globally.

We would like to reassure you that there are no consequences for ongoing clinical trials arising from our decision to withdraw the above mentioned application.

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

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

Yours sincerely,