



Research & Development of Anti-Infectives

Date: 21 October 2009

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

Subject: Withdrawal of MERSAREX[®] (Iclaprim) 12.8 mg/ml Concentrate for Solution for Infusion

EMA procedure number – EMA/H/C/001057

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Arpida A/S has taken the decision to withdraw the application for Marketing Authorisation of MERSAREX[®] (iclaprim) 12.8 mg/ml Concentrate for Solution for Infusion, which was intended to be used for treatment of complicated skin and soft tissue infections.

This withdrawal is based on the following reason:

- The CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance

It is not expected that this withdrawal will have any consequences on ongoing clinical trials and compassionate use programmes. Additional information on future plans for development of Mersarex is not presently available.

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 EMA website.

Yours sincerely,