sanofi aventis

recherche & développement

6 September, 2006

Dr Daniel BRASSEUR
European Medicines Agency
7 Westferry Circus, Canary Wharf
London E14 4HB
United Kingdom

Subject: Withdrawal of MULTAQ, (dronedarone) 400 mg film-coated tablets
EMEA/H/C/676

Dear Dr Brasseur,

I would like to inform you that, at this point of time, sanofi-aventis has taken the decision to withdraw the application for Marketing Authorisation of MULTAQ (dronedarone), 400 mg film-coated tablets, intended to be used for the treatment of atrial fibrillation and atrial flutter.

This withdrawal is based on the fact that the CHMP has requested additional clinical data in order to adequately assess the benefit risk balance of the product. The additional clinical data requested cannot be provided within the timeframe of the current procedure.

The ongoing clinical program is continuing as planned. Sanofi-aventis reserves the right to resubmit an application for Marketing Authorisation in this and/or other indications once data from this program become available.

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

Yours sincerely,

Corporate Regulatory Affairs
Sanofi-aventis