

recherche à développement

To:

Dr Eric ABADIE EMEA 7 Westferry Circus Canary Wharf London, E14 4HB United Kingdom

Chilly-Mazarin, May 23rd, 2008

Subject: Withdrawal of initial marketing authorisation application - AQUILDA (satavaptan), 5 and 25 mg film-coated tablets - EMEA/H/C/873

Dear Dr Abadie.

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 AQUILDA (satavaptan), 5 and 25 mg film-coated tablets which was intended to be used for the treatment of euvolemic and hypervolemic dilutional hyponatremia.

The withdrawal is based on the following reason:

• CHMP's request for additional information on the therapeutic safety and efficacy of satavaptan.

Sanofi-aventis is currently developing this information but the results will not be available before 2009.

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,

sanofi aventis

