GlaxoSmithKline Research
& Development Limited
Stockley Park West
Uxbridge
Middlesex
UB11 1BU

Tel. +44 (0)20 8990 9000
www.gsk.com

Dr E Abadie
Chair of Committee for Human Medicinal Products
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB

25 th September 2009

Dear Dr Abadie

Subject: Withdrawal of Marketing Authorisation Application for ZUNRISA (as casopitant mesilate), 50 mg & 150 mg film coated tablets - EMEA/H/C/1040

I would like to inform you that, at this point in time, Glaxo Group Limited has taken the decision to withdraw the application for the EU Marketing Authorisation for Zunrisa (as casopitant mesilate), 50 mg & 150 mg film coated tablets, which was intended to be used in the prevention of Post-operative Nausea and Vomiting and Chemotherapy Induced Nausea and Vomiting.

Glaxo Group Ltd, has made this decision based on the company's assessment that further safety data, as requested by the US Regulatory Authority, is required to support the registration of casopitant on a worldwide basis and that it would take considerable time to produce these data. Consequently, all on-going regulatory files for casopitant are being withdrawn.

At the time of the withdrawal only one clinical trial with casopitant is on-going and GSK has taken the decision to stop this trial. Doctors involved in stopping this trial are being provided with full support.

Registered in England & Wales
No. 835139

Registered office
980 Great West Road
Brentford, Middlesex. TW8 9GS

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

I agree that this letter may be published on the EMEA website.