GlaxoSmithKline Research
& Development Limited
New Frontiers Science Park
Third Avenue
Harlow
Essex
CM19 5AW

Tel. +44 (0)1279 622000
Fax. +44 (0)1279 644100
www.gsk.com

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

28th July 2009

Dear Dr Abadie

Subject: Withdrawal of Marketing Authorisation Application for BOSATRIA (mepolizumab powder for solution for infusion, 250mg/vial) - EMEA/H/C/1069

I would like to inform you that, at this point in time, Glaxo Group Limited has taken the decision to withdraw the application for Marketing Authorisation for Bosatria (mepolizumab powder for solution for infusion, 250mg/vial), which was intended to be used for the treatment of hypereosinophilic syndrome (HES) in adult patients without the FIP1L1-PDGFR fusion gene, to reduce or eliminate the need for corticosteroid therapy and to reduce blood eosinophil count.

Glaxo Group Limited have taken this decision based on the CHMP's view that the data available to date do not allow the committee to conclude on a positive risk/benefit balance for mepolizumab in HES at this point in time.

The Company will continue to make mepolizumab available to patients with HES in ongoing clinical trials (including the compassionate use and named patient programmes and Study MHE100901) for as long as the patients and their treating physicians believe that they are benefiting from continued treatment. Ongoing clinical studies in other indications will continue.

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

Registered in England & Wales
No. 835139

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

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