TEVA PHARMA B.V.

Dr Tomas Salmonson
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

04 November 2014

Subject: **Withdrawal Egranli, Balugrastim, 40 mg, solution for injection EMEA/H/C/002637**

Dear Dr Salmonson,

We would like to inform you that, at this point of time, Teva Pharma B.V. has taken the decision to withdraw the application for Marketing Authorisation of Egranli (balugrastim), 40 mg, solution for injection, which was intended to be used for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of myeloid leukaemia and myelodysplastic syndromes).

This withdrawal is based on the following reasons:

Teva Pharma B.V. has taken this decision based on the company's marketing strategy. The company wishes to focus its resources to other EMA and global regulatory projects.

Please note that there will be no impact on patient safety or treatment programmes as there are no ongoing clinical trials or compassionate use programmes using Egranli. Further, Teva Group already markets alternative treatment options for chemotherapy-induced neutropenia in the European Union.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

We agree for this letter to be published on the EMA website.

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