GEDEON RICHTER

Established in 1901

Date: 16 November 2016

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

Subject: Withdrawal of Efgratin (pegfilgrastim), 6 mg/0.6 ml, solution for injection
EMEA/H/C/004023

Dear Dr. Tomas Salmonson,

We would like to inform you that, at this point of time, Gedeon Richter Plc. has taken the decision to withdraw the application for Marketing Authorisation of Efgratin, (pegfilgrastim), 6 mg/0.6 ml, solution for injection, which was intended to be used for reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy.

This withdrawal is based on the following reason:

> After the oral explanation the CHMP considered that the data provided do not allow the committee to conclude a positive benefit risk assessment.

Based on the discussion with the (Co)Rapporteurs and the CHMP, the Company decided to continue the development and follow their advice to eliminate their only remaining uncertainty.

We would like to recognize the vast insights we have gained during the review process our product has undergone. Such perspective will guide our thinking as we continue with the development of this product. Accordingly, we acknowledge and thank the CHMP members and our (Co)Rapporteurs for the support and guidance they have provided.

There are no ongoing clinical trials or compassionate use programmes for this product.

We reserve the right to make further submissions at a future date.

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

Yours sincerely,

[redacted]

[redacted]