SANDOZ
a Novartis company

To Tomas Salmonson, PhD (CHMP Chair)
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

[redacted]

[redacted]

Subject: Withdrawal of Zioxtenzo (pegfilgrastim), 6mg/0.6mL, solution for injection - EMEA/H/C/004211

Dear Dr Salmonson,

We would like to inform you that, at this point of time, Sandoz GmbH has taken the decision to withdraw the application for Marketing Authorisation of Zioxtenzo (pegfilgrastim), 6mg/0.6mL, 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.

This withdrawal is based on the following reason:

Sandoz will not be able to provide the additional information required by the CHMP within the regulatory timeframe for this procedure. Sandoz will continue to collaborate with EMA to make this product available to the patients in the EEA and intends to resubmit the application as soon as the outstanding information is available.

The company confirms that this withdrawal does not impact ongoing clinical trials. There are no compassionate use programs for this product.

Sandoz would like to use this opportunity to sincerely thank the EMA as well as the Rapporteurs for their valuable support, fruitful discussions and helpful guidance throughout the entire procedure.

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

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

Yours sincerely,

Sandoz GmbH

[redacted]