STADA Arzneimittel AG · Stadastraße 2–18 · 61118 Bad Vilbel

Dr. Harald Enzmann (CHMP chair)
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

20-December-2018

Subject: Withdrawal of Cavoley (pegfilgrastim), 0,6 mg/ml, solution for injection – EMEA/H/C/005008

Dear Dr. Enzmann,

We would like to inform you that, at this point in time, STADA Arzneimittel AG has taken the decision to withdraw the application for Marketing Authorisation Application for Cavoley (pegfilgrastim), 0,6 mg/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 decision was taken because STADA Arzneimittel AG cannot address the major objections, raised by the CHMP in the Day 120 List of Questions to support a positive risk/benefit assessment in the proposed indication within the timeframe of the Centralised Procedure.

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

We would like to thank the Rapporteur, Co-Rapporteur, EMA, PRAC and CHMP members for the time and effort dedicated in their review and the guidance provided during the 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 European Medicines Agency website.

Yours sincerely,

STADA Arzneimittel AG

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