TGRD (Europe)

Date: 20 June 2013

Dr Tomas Salmonson
European Medicines Agency
Loading Dock
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United Kingdom

Subject: Withdrawal of Marketing Authorisation Application for Omontys (peginesatide) 1, 2, 3, 4, 5, 6 and 8 mg per 0.5 ml, solution for injection - EMEA/H/C/002600

Dear Dr Tomas Salmonson,

I would like to inform you that, at this point of time, Takeda Global Research and Development Centre (Europe) Limited has taken the decision to withdraw the application for Marketing Authorisation (MAA) of Omontys (peginesatide) 1, 2, 3, 4, 5, 6 and 8 mg per 0.5 ml solution for injection, which was intended to be used for treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adult patients undergoing dialysis.

This withdrawal is based on the following reason: post-marketing reports of serious hypersensitivity reactions, including anaphylaxis, some of which were life-threatening or fatal, following administration of Omontys in the United States of America (USA), while the EU MAA was under review. Such severe reactions had not been observed during clinical trials. An investigation into the root cause of the reactions was initiated and is currently ongoing. Takeda has determined that it will not be able to complete the investigation and propose appropriate risk mitigation measures within the MAA procedure timeframe.

There is one ongoing clinical study in CKD patients with pure red cell aplasia. Given that most of the reported serious hypersensitivity reactions occurred after first administration, recruitment of new subjects has been halted. Subjects already in the study have been on treatment between approximately 1 and up to 7 years and have the option to continue receiving Omontys.

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

I agree for this letter to be published on the EMEA website.

Yours sincerely,

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