28 January 2015
EMA/CHMP/68384/2015
Committee for Medicinal Products for Human Use (CHMP)

Assessment report

Tasermity

International non-proprietary name: sevelamer hydrochloride

Procedure No. EMEA/H/C/003968/0000

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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Administrative information

Name of the medicinal product:	Tasermity
Applicant:	sanofi-aventis recherche et développement Gooimeer 10 1411 DD Naarden NETHERLANDS
Active substance:	Sevelamer hydrochloride
International Nonproprietary Name:	Sevelamer hydrochloride
Pharmaco-therapeutic group (ATC Code):	Sevelamer hydrochloride (V03AE02)
Therapeutic indication(s):	Sevelamer hydrochloride is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Sevelamer hydrochloride should be used within the context of a multiple therapeutic approach, which could include calcium supplements, 1,25-dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.
Pharmaceutical form(s):	Film-coated tablet
Strength(s):	800 mg
Route(s) of administration:	Oral use
Packaging:	bottle (HDPE)
Package size(s):	180 tablets

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List of abbreviations

CHMP	Committee for Medicinal Products for Human Use
EMA	European Medicines Agency
ERA	Environmental Risk Assessment
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan

1. Background information on the procedure

1.1 Submission of the dossier

The applicant sanofi-aventis recherche et développement submitted on 5 June 2014 an application for Marketing Authorisation to the European Medicines Agency (EMA) for Tasermity, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMA/CHMP on 20 February 2014.

The applicant applied for the following indication:

> *Sevelamer hydrochloride is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Sevelamer hydrochloride should be used within the context of a multiple therapeutic approach, which could include calcium supplements, 1,25-dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.*

The legal basis for this application refers to:

Article 10(c) of Directive 2001/83/EC – relating to informed consent from a marketing authorisation holder for an authorised medicinal product.

The application submitted is composed of administrative information together with a letter from Genzyme Europe BV allowing use to be made of relevant quality, non-clinical and/or clinical data of the original marketing authorisation for Renagel.

This application was submitted, in accordance with Article 82.1 of Regulation (EC) No 726/2004**,** as a multiple of Renagel authorised on 28 January 2000.

Information on Paediatric requirements

Not applicable

Information relating to orphan market exclusivity

Similarity

Pursuant to Article 8 of Regulation (EC) No. 141/2000 and Article 3 of Commission Regulation (EC) No 847/2000, the applicant did not submit a critical report addressing the possible similarity with authorised orphan medicinal products because there is no authorised orphan medicinal product for a condition related to the proposed indication.

Market exclusivity

Not applicable

Scientific Advice

The applicant did not seek scientific advice at the CHMP.

Licensing status

The product was not licensed in any country at the time of submission of the application. The original medicinal product Renagel was approved in the EU on 28 January 2000.

1.2 Manufacturers

Manufacturers responsible for batch release

Genzyme Ireland Limited
IDA Industrial Park
Old Kilmeaden Road
Waterford
IRELAND

Genzyme Limited
37 Hollands Road
Suffolk
Haverhill
CB9 8PU
UNITED KINGDOM

1.3 Steps taken for the assessment of the product

The Rapporteur and Co-Rapporteur appointed by the CHMP were:

Rapporteur: Janne Kolmi Co-Rapporteur: Bart Van der Schueren

- The application was received by the EMA on 5 June 2014.
- The procedure started on 27 July 2014.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 1 September 2014 (Annex 1).
- During the meeting on 25 September 2014, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 25 September 2014 (Annex 2).
- During the meeting on 23 October 2014, the CHMP agree to amend the consolidate List of Questions deleting the question on medication errors, since this one was no longer applicable as the Applicant apply for a change of name.
- The applicant submitted the responses to the CHMP List of Outstanding Issues on 17 October 2014.
- During the meeting on 23 October 2014, the CHMP adopted updated List of Questions (Annex 3).

- The Rapporteur circulated the Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 13 November 2014 (Annex 4).
- During the meeting on 18 December 2014, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Tasermity.
- The CHMP adopted via written procedure a revised positive opinion for granting a Marketing Authorisation on 28 January 2015.

2. Scientific discussion

2.1 Introduction

Hyperphosphataemia is one the most common sequalae of chronic kidney disease. According to the epidemiologic data, hyperphosphataemia is associated with increased mortality and cardiovascular disease events both in general population and especially in chronic kidney disease patients. Preclinical and clinical data support the hypothesis that this association is mediated by cardiovascular calcification and by other detrimental effects of hyperphosphatemia on vasculature and heart. Based on these findings, the main renal guidelines recommend strongly the restriction of dietary phosphorus and/or the use oral phosphate binders to achieve the recommended serum phosphorus level in dialysis patients and, with some reservations, also in pre-dialysis patients. Currently available authorised therapeutic agents for hyperphosphatemia in Europe include calcium-containing phosphate binders (calcium carbonate; calcium acetate; combination of calcium acetate and magnesium carbonate), lanthanum carbonate and ion-change resins including sevelamer hydrochloride, sevelamer carbonate and colestilan.

This Marketing Authorisation Application concerns Tasermity 800 mg tablets, in the treatment of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. It is a duplicate application to the marketing authorisation (MA) of Renagel (EMEA/H/C/000254)

The active substance is sevelamer hydrochloride (ATC code: V03AE02; Pharmacotherapeutic Group: Treatment of hyperphosphataemia).

The application has been submitted in accordance with Regulation (EC) No 726/2004 and is regarded to have automatic access for substance already authorised via Centralised Procedure. Eligibility based on automatic access was confirmed by EMA on 20 February 2014. The CHMP appointed during February 2014 meeting Dr Janne Komi as Rapporteur and Dr. Bart Van der Schueren as Co-Rapporteur.

The legal basis of this application is Article 10c of Directive 2001/83/ EC, Informed consent application, and accordingly a complete Module 1 is submitted. Letter of consent from the MAH of Renagel has been enclosed. The Applicant Sanofi-aventis recherché et developpement and Genzyme Europe B.V. (a Sanofi company) is the marketing authorisation holder of the reference medicinal product Renagel.

2.2 Quality aspects

As Tasermity is submitted under an informed consent application, article 10(c) of directive 2001/83/EC, only module 1 is provided and module 3 of the duplicate dossier cross-refers to the up-to-date module 3 of the original dossier (Renagel), which have been assessed and approved, including all post-marketing procedures.

2.3 Non-clinical aspects

2.3.1 Introduction

Since this application is an informed consent of the Renagel application, the non-clinical data in support of the Tasermity application are identical to the up-to-date quality data of the Renagel dossier, which have been assessed and approved, including all post-marketing procedures.

2.3.2 Environmental risk assessment

In accordance with the scope described in the CHMP guideline, given that this application is for products that are already authorized, the absence of a phased approach ERA as specified in the guideline, is considered justified in that the total quantity of the drug substance sevelamer hydrochloride is not expected to increase upon approval of this marketing authorization. Consequently, marketing approval would not add to the environmental impact.

2.2.3 Conclusion on the non-clinical aspects

In this informed consent application, there are no issues related to the non-clinical data, which have been assessed for Renagel application and adequately reflected in the Product Information.

2.4 Clinical aspects

As Tasermity is submitted under an informed consent application, article 10(c) of directive 2001/83/EC, only module 1 is provided and module 2 of the duplicate dossier cross-refers to the up-to-date module 2 of the original dossier (Renagel), which has been assessed and approved. No new clinical data is provided.

2.5 Clinical safety

The RMP version 5 being strictly identical to the RMP approved for the reference product, therefore no further assessment of the present RMP is deemed necessary.

2.6 Pharmacovigilance

Detailed description of the pharmacovigilance system

The CHMP considered that the Pharmacovigilance system as described by the applicant fulfils the legislative requirements.

2.7 Risk Management Plan

The CHMP received the following PRAC Advice on the submitted Risk Management Plan:

The CHMP considered that the risk management plan version 5 is acceptable.

3. Benefit-Risk Balance

This Marketing Authorisation application for Tasermity has been submitted by Genzyme Europe BV as an informed consent application in accordance with Article 10c of Directive 2011/83/EC, as amended.

As a consequence, quality, safety and efficacy of the Tasermity medicinal product are identical to the up-to-date quality, non-clinical and clinical profile of Renagel. The application for Tasermity concerns the identical strengths to those approved for Renagel and consists of only Module 1. Information on the scientific discussion can be found on the Renagel CHMP assessment reports and in the European Public Assessment Report (EPAR) published on the EMA website.

Consequentially, and in line with the assessment of data undertaken in the framework of the Renagel initial marketing authorisation application as well as within all post-autorisation procedures, the CHMP considers that the benefit/risk balance for Tasermity is positive.

4. Recommendations

Outcome

Based on the CHMP review of data on quality, safety and efficacy, the CHMP considers by consensus that the risk-benefit balance of Tasermity in the treatment for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis is favourable. Sevelamer hydrochloride should be used within the context of a multiple therapeutic approach, which could include calcium supplements, 1,25-dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.

The CHMP therefore recommends the granting of the marketing authorisation subject to the following conditions:

Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Conditions and requirements of the marketing authorisation

- **Periodic Safety Update Reports**

The marketing authorisation holder shall submit periodic safety update reports for this product in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

Conditions or restrictions with regard to the safe and effective use of the medicinal product

- **Risk management system (RMP)**

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.
- When the submission of a PSUR and the update of a RMP coincide, they should be submitted at the same time.