EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2011
EMA/437167/2011

Assessment report

Leganto

International Nonproprietary Name: rotigotine

Procedure No. EMEA/H/C/002380

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

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1. Background information on the procedure

1.1. Submission of the dossier

The applicant Schwarz Pharma Ltd. submitted on 28 January 2011 an application for Marketing Authorisation to the European Medicines Agency (EMA) for Leganto, 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 during the CHMP meeting on 19-22 July 2010.

The applicant applied for the following indications:

"Leganto is indicated for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in adults.
Leganto is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or 'on-off' fluctuations)."

The legal basis for this application refers to:

Article 10(c) of Directive 2001/83/EC, as amended – relating to informed consent from the marketing authorisation holder Schwarz Pharma Ltd for the authorised medicinal product Neupro (EU/1/05/331/001-055).

The application submitted is composed of administrative information, quality, non-clinical and clinical data with a letter from a MAH Schwarz Pharma Ltd allowing use to be made of relevant quality, non-clinical and/or clinical data.

Information on Paediatric requirements

Not applicable.

Information relating to Orphan Market Exclusivity

Not applicable.

Scientific Advice

The applicant did not seek scientific advice at the CHMP.

Licensing status

The initial product Neupro has been given a Community Marketing Authorisation on 15 February 2006.

1.2. Steps taken for the assessment of the product

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

Rapporteur: **Beatriz Silva Lima**

Co-Rapporteur: **Barbara van Zwieten-Boot**

- The application was received by the EMA on 28 January 2011.
- The procedure started on 13 February 2011.

- The Rapporteur's first Assessment Report was circulated to all CHMP members on 21 March 2011. The Co-rapporteur's first Assessment Report was circulated to all CHMP members on 21 March 2011.
- The Rapporteurs circulated the Joint Assessment Report to all CHMP members on 6 April 2011.
- During the meeting on 11-14 April 2011, 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 Leganto on 14 April 2011. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 12 April 2011.

2. Scientific discussion

2.1. Introduction

This marketing authorisation application for Leganto (rotigotine) has been submitted by Schwarz Pharma Ltd as an informed consent application in accordance with Article 10c of Directive 2001/83/EC, as amended.

The MAH (Schwarz Pharma Ltd) for Neupro, which was authorised on 15 February 2006, and submitted under Article 8(3) of Directive 2001/83/EC as amended, provided consent to make use of the pharmaceutical, non-clinical and clinical documentation of the initial dossier of this authorised product and any subsequent post-marketing procedures submitted, assessed and approved.

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

The approved indications are:

“Neupro is indicated for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in adults.
Neupro is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson’s disease as monotherapy (i.e. without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or ‘on-off’ fluctuations).”

2.2. Quality aspects

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

2.3. Non-clinical aspects

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

The applicant has referred to the originators current Environmental Risk Assessment (ERA) dated 14 October 2009, which was also provided in the Leganto dossier. The assessment conclusions of the originators ERA can only be accepted for the Leganto application under the premise that the use of Leganto will not result in an increased use of rotigotine.

2.4. Clinical aspects

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

2.5. Pharmacovigilance

Detailed description of the pharmacovigilance system

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

Risk Management Plan

The applicant submitted a risk management plan (version 8.0) identical to that for Neupro.

The CHMP, having considered the data submitted in the application, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information.

User consultation

The Package Leaflet for Neupro has been successfully user tested. For the Leganto application, a bridging report has been submitted. The bridging report submitted by the applicant has been found acceptable. The proposed Package Leaflet for Leganto is identical to the Package Leaflet for Neupro except for the product-specific information such as the product name and the list of local representatives. Based on the bridging report, the CHMP considered that the requirements concerning the Package Leaflet and the consultation with target patients groups are fulfilled for Leganto.

2.6. Benefit-Risk Balance

Since this application has been submitted by Schwarz Pharma Ltd as an informed consent application to Neupro in accordance with Article 10c of Directive 2001/83/EC, as amended, the CHMP considered that the benefit-risk balance of Leganto (1 mg/24 h, 2 mg/24 h, 3 mg/24 h, 4 mg/24 h, 6 mg/24 h and 8 mg/24 h) transdermal patch was favourable and therefore recommended the granting of the marketing authorisation for the following indications:

"Leganto is indicated for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in adults.
Leganto is indicated for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or 'on-off' fluctuations)."

2.7. Recommendation

Based on the CHMP review of data on quality, safety and efficacy, the CHMP considered by consensus that the risk-benefit balance of Leganto in the treatment of Restless Legs Syndrome and Parkinson's disease was favourable and therefore recommended the granting of the marketing authorisation.