European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 20 March 2008
Doc.Ref. EMEA/CHMP/138637/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
EXTAVIA
International Nonproprietary Name (INN): ***interferon beta-1b***

On 19 March 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Extavia, 250 microgram/ml, powder and solvent for solution for injection intended for treatment of:

- Patients with a single demyelinating event with an active inflammatory process, if it is severe enough to warrant treatment with intravenous corticosteroids, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.
- Patients with relapsing-remitting multiple sclerosis and two or more relapses within the last two years.
- Patients with secondary progressive multiple sclerosis with active disease, evidenced by relapses.

The applicant for this medicinal product is Novartis Europharm Ltd.
This application is an informed consent from a marketing authorisation holder for an authorised medicinal product (Betaferon). A letter of consent from Bayer Schering Pharma AG has been submitted by the Applicant, which authorizes the use of the pharmaceutical, pre-clinical and clinical documentation of Betaferon in support of this application.

The active substance of Extavia is interferon beta-1b, a cytokine (ATC code: L03AB08).

The Applicant has confirmed that they will have permanent access to the Betaferon documentation. Therefore, no data have been submitted with this application, which only contains documentation for Module 1.

In the studies with Betaferon which supported this application, the following results have been obtained: in patients with relapsing remitting MS, interferon beta-1b was more effective than placebo in reducing the number of annual relapses.
In patients with secondary progressive MS, one of the two studies showed a significant delay in the time to disability progression and in the time to becoming wheelchair bound. In the second trial, no delay in the time to disability progression was seen. In both trials, interferon beta-1b showed a reduction in the number of clinical relapses.
In patients with a single demyelinating event, interferon beta-1b was shown to reduce the risk of developing clinically definite MS.

The most common side effects are flu-like symptoms and injection site reactions.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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A pharmacovigilance plan for Extavia, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “Treatment of patients with a single demyelinating event with an active inflammatory process, if it is severe enough to warrant treatment with intravenous corticosteroids, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis .Treatment of patients with relapsing-remitting multiple sclerosis and two or more relapses within the last two years. Treatment of patients with secondary progressive multiple sclerosis with active disease, evidenced by relapses”.

It is proposed that Extavia is prescribed by physicians experienced in the treatment of Multiple Sclerosis.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Extavia and therefore recommends the granting of the marketing authorisation.