22 May 2014
EMA/CHMP/276483/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Plegridy

peginterferon beta-1a

On 22 May 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Plegridy, 63 mcg, 94 mcg and 125 mcg, solution for injection intended for the treatment of relapsing remitting multiple sclerosis. The applicant for this medicinal product is Biogen Idec Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Plegridy is peginterferon beta-1a, a pegylated form of an interferon (L03AB13) with immunomodulatory activity. The exact mechanism of action in the treatment of multiple sclerosis is not fully understood, but beta interferons have been shown to increase anti-inflammatory and reduce pro-inflammatory immune responses.

The benefits with Plegridy are its ability to reduce the relapse rate in relapsing-remitting multiple sclerosis. The most common side effects are injection site erythema, influenza like illness, fever, headache, myalgia (muscle pain), chills, injection site pain, asthenia (feeling weak and tired), injection site pruritus, and arthralgia (Pain in your joints, arms, legs or neck).

A pharmacovigilance plan for Plegridy will be implemented as part of the marketing authorisation.

The approved indication is: "Plegridy is indicated in adult patients for the treatment of relapsing remitting multiple sclerosis". It is proposed that Plegridy be 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 (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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