20 January 2011
EMA/26661/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Gilenya

fingolimod

On 20 January 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Gilenya, 0.5 mg, hard capsule intended for the treatment of adult patients with relapsing-remitting multiple sclerosis with high disease activity. The applicant for this medicinal product is Novartis Europharm 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 Gilenya is fingolimod, a selective immunosuppressant (ATC code: L04AA27) acting as a sphingosine 1-phosphate (S1P) receptor modulator. Fingolimod is metabolised to the active metabolite fingolimod phosphate, a functional antagonist of S1P receptors on lymphocytes. Fingolimod phosphate blocks the capacity of lymphocytes to egress from lymph nodes, causing a redistribution, rather than depletion, of lymphocytes. This redistribution reduces the infiltration of pathogenic lymphocyte cells into the central nervous system.

The benefits with Gilenya are its ability in reducing the number of relapses in patients with relapsing-remitting multiple sclerosis. The most common side effects (seen in more than 1 patient in 10) are influenza viral infections, headache, diarrhoea, back pain, cough and elevated liver enzyme (known as ALT). Other common side effects (seen in between 1 and 10 patients in 100) that could be or could become serious are herpes virus infection (shingles or herpes zoster), lymphopenia, leucopenia (reduced white blood cells), bradycardia (slow heartbeat), atrioventricular block (irregular heart rhythm), bronchitis and gastroenteritis.

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

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The approved indication is:

"Gilenya is indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups:

- Patients with high disease activity despite treatment with a beta-interferon.

These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least 1 relapse in the previous year while on therapy, and have at least 9 T2-hyperintense lesions in cranial MRI or at least 1 Gadolinium-enhancing lesion. A "non-responder" could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.

or

- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI".

It is proposed that Gilenya 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 (SmPC), 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 there to be a favourable benefit to risk balance for Gilenya and therefore recommends the granting of the marketing authorisation.