EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 May 2016
EMA/CHMP/181854/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tysabri

natalizumab

On 26 May 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Tysabri. The marketing authorisation holder for this medicinal product is Biogen Idec Ltd.

The CHMP adopted changes to the existing indication as follows[2]:

"TYSABRI is indicated as single disease modifying therapy in **adults with** highly active relapsing remitting multiple sclerosis for the following patient groups:

- ~~Adult~~ Patients ~~aged 18 years and over~~ with high**ly active** disease activity despite **a full and adequate course of** treatment with **at least one disease modifying therapy (DMT) (for exceptions and information about washout periods see sections 4.4 and 5.1)** ~~a beta-interferon or glatiramer acetate~~.

  ~~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 or glatiramer acetate. 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 Magnetic Resonance Image (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

- ~~Adult~~ Patients ~~aged 18 years and over~~ 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."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] New text in bold, removed text strikethrough

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