EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 September 2010
EMA/598746/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Mabthera

rituximab

On 23 September 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Mabthera. The marketing authorisation holder for this medicinal product is Roche Registration Ltd. They may request a re-examination of the CHMP opinion, provided that they notify the European Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to an indication as follows:
MabThera maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.

The CHMP adopted a new contraindication as follows:

Patients in a severely immunocompromised state.

Detailed conditions for the use of this Medicines 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 the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Mabthera will be as follows[2]:

MabThera is indicated in adults for the following indications:

Non-Hodgkin's lymphoma (NHL)

MabThera is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy.

MabThera maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

[2] The text in bold represents the new or the amended indication.

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MabThera monotherapy is indicated for treatment of patients with stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after chemotherapy.

MabThera is indicated for the treatment of patients with CD20 positive diffuse large B cell non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy.

Chronic lymphocytic leukaemia (CLL)

MabThera in combination with chemotherapy is indicated for the treatment of patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia. Only limited data are available on efficacy and safety for patients previously treated with monoclonal antibodies including MabThera or patients refractory to previous MabThera plus chemotherapy.

See section 5.1 for further information.

Rheumatoid arthritis

MabThera in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARD) including one or more tumour necrosis factor (TNF) inhibitor therapies.

For information, the full contraindications for MABTHERA will be as follows[3]:

Contraindications for use in non-Hodgkin's lymphoma and chronic lymphocytic leukaemia
Hypersensitivity to the active substance or to any of the excipients or to murine proteins.
Active, severe infections (see section 4.4).
Patients in a severely immunocompromised state

Contraindications for use in rheumatoid arthritis
Hypersensitivity to the active substance or to any of the excipients or to murine proteins.
Active, severe infections (see section 4.4).
Patients in a severely immunocompromised state
Severe heart failure (New York Heart Association Class IV) or severe, uncontrolled cardiac disease (see section 4.4 regarding other cardiovascular diseases).

[3] The text in bold represents the new or the amended contraindication.