Positive benefit-risk balance of MabThera confirmed by European Medicines Agency

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Information on Medicinal Product

MabThera is indicated in non-Hodgkin's lymphoma (follicular lymphoma and diffuse large B-cell lymphoma), chronic lymphocytic leukaemia (CLL) and rheumatoid arthritis. It is authorised in Malta and is available in hospital as a concentrate for solution for infusion of in 100mg and 500mg doses. Rituximab (the active substance) is an antineoplastic monoclonal antibody with ATC code L01XC02.

Information from European Medicines Agency about the safety concern

- The review of MabThera was initiated after the unexpected detection of *Leptospira licerasiae* during the early stages (pre-harvest) manufacturing process of rituximab in bioreactors at Vacaville (the manufacturing site). The contaminant was not detected at later stages of manufacturing of the active substance or the finished product, and all material in which the bacteria had been detected was discarded.
- *Leptospira licerasiae* is a bacterial species that can cause leptospirosis, a water-borne disease transmitted from animals to humans.
- The Committee Medicinal Products for Human use (CHMP) reviewed all available quality data provided by the company and looked for the root cause of the contamination concluding that *L. licerasiae* had most likely been introduced into the cell culture media used in the bioreactors through personnel acting as external carriers and/or through the media preparation process itself.
- The Committee was reassured that the findings were not associated with any clinically relevant risk for patients treated with MabThera, as no bacteria were detected in the active substance or in the finished product, and that the manufacturing process is robust enough to eliminate any bacteria and proteins released by the bacteria.

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

- A European Commission decision on the opinion of the CHMP will be issued in due course.

In Malta

For Healthcare Professionals

- The benefit-risk balance of MabThera made using the active substance produced at the Vacaville site continues to be positive.

Advice for Patients

- Patients should continue treatment with this product under the supervision of their doctor.

For more information please see the **press release** and **question-and-answer document** issued by the European Medicines Agency and the current European public assessment report for MabThera which can be found on the Agency's website: **ema.europa.eu/Find medicine/Human medicines/European public assessment reports.**

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on MabThera. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/pub/adr.doc** or to the marketing authorisation holder or their local representatives. '

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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