



COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
REMOVAB

International Nonproprietary Name (INN): *catumaxomab*

On 19 February 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Removab, 10 microgram and 50 microgram concentrate for solution for infusion intended for treatment of malignant ascites. The applicant for this medicinal product is Fresenius Biotech GmbH.

The active substance of Removab is catumaxomab, a monoclonal antibody (ATC code: L01XC09). The antibody possesses 2 different antigen binding sites. One targets the human epithelial cell adhesion molecule (EpCAM), which is found in the majority of epithelial tumours. The other targets human CD3, a molecule that is expressed on T-lymphocytes. Another region of the antibody binds to receptors that are expressed on other cells of the immune system. Binding of catumaxomab to EpCAM-positive tumour cells, T-lymphocytes and other cells of the immune system is thought to bring them close together and this might lead to the reduction of tumour cells via multiple mechanisms.

The benefit with Removab is its reduction in the need for paracenteses, in patients with malignant ascites. The most common side effects are abdominal pain, fever, feeling sick (nausea), vomiting and diarrhoea, tiredness, pain and chills, and reduction in number of lymphocytes.

A pharmacovigilance plan for Removab as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Removab is indicated for the intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible". Removab must be administered under the supervision of a physician experienced in the use of anti-neoplastic medicinal products.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 that there is a favourable benefit to risk balance for Removab and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.