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Increased survival with new treatment for cancer of the lymphatic system

EU health committee issues positive opinion on use of MabThera in aggressive Non-Hodgkin's Lymphoma

The European Committee for Proprietary Medicinal Products (CPMP¹) today issued a positive opinion recommending the granting of a marketing authorisation for the novel anti-cancer drug MabThera (rituximab) for the treatment of aggressive non-Hodgkin's lymphoma (NHL).

The availability of MabThera in this indication gives hope of increased survival for hundreds of thousands of sufferers of this cancer of the lymphatic system. Globally, approximately 1.5 million people are diagnosed with NHL and nearly 55% of them have the aggressive - fast growing - form of the disease. NHL is the third fastest growing cancer behind melanoma of the skin and lung cancer.

The positive opinion is based on the use of MabThera in combination with standard chemotherapy (called CHOP). Dr Ed Holdener, Head of Global Development for Roche Pharmaceuticals said: "This is the first new drug combination in more than 20 years to show an improvement in overall survival for patients with this rapidly fatal cancer. Pivotal study results to date indicate that patients increase their chance of cure when treated with MabThera plus standard chemotherapy, when compared with standard chemotherapy alone. After 18 months of follow-up, 74% of patients were alive and well with the MabThera plus standard therapy combination, compared to 62% after standard therapy alone."

The positive opinion from the CPMP recommending the granting of a marketing authorisation for MabThera in aggressive NHL is based on interim results from the pivotal (GELA) study². The results also showed a complete remission rate of 71% (MabThera plus standard chemotherapy) vs. 59% (standard chemotherapy alone). Patients experiencing a complete remission have a higher chance of being cured.

Two year follow up results are due to be presented at the American Society of Hematology meeting, in Orlando 7-11 December, where it is expected that there will be confirmation of the 18 month interim data.

MabThera was co-developed by Roche, Genentech and IDEC Pharmaceuticals. Since its introduction in 1997 for low grade non-Hodgkin's lymphoma MabThera (in the USA: Rituxan) has achieved rapid acceptance by doctors and patients. MabThera is Roche's second largest prescription product just four years after its first launch.

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-based healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the diagnosis, prevention and treatment of diseases, thus enhancing patients' well-being and quality of life. Roche's oncology franchise includes three products with survival benefit: Xeloda (colorectal cancer, breast cancer), Herceptin (breast cancer), MabThera (non-Hodgkin's lymphoma). It also includes NeoRecormon (anaemia in various cancer settings), Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma), Neupogen (neutropenia) and Kytril (chemotherapy and radiotherapy-induced nausea).

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¹ The CPMP is the scientific body of the European Medicines Evaluation Agency (EMA), and its opinions usually serve as the basis for European Commission approvals.

² This phase III study was conducted by Groupe d'Etude des Lymphomes de l'Adulte (GELA), a large cancer co-operative group of more than 110 institutions in France, Belgium and Switzerland. The interim analysis analysed 328 out of the enrolled 399 previously untreated elderly patients (60 years or older) with aggressive NHL. Patients were randomised to receive standard CHOP chemotherapy alone (every three weeks for eight cycles) or MabThera (375 mg/m²) plus CHOP. MabThera was administered at the same time as CHOP for eight cycles.