Media Release

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Roche files MabThera Marketing Application in Europe for use in first line indolent Non-Hodgkin's Lymphoma (NHL)

Roche today announced the submission of a Marketing Authorisation application to the European Health Authorities for MabThera (rituximab) as a treatment for first line indolent non-Hodgkin's lymphoma in combination with conventional chemotherapy. The application is based on data from a phase III study in which the combination of MabThera plus CVP (cyclophosphamide, vincristine and prednisolone) chemotherapy was significantly superior to CVP chemotherapy alone:

- Time to treatment failure was significantly prolonged by more than 1 ½ years: 26 months (MabThera plus CVP) versus 7 months (CVP);
- Freedom from disease progression was nearly doubled: 27 months (MabThera plus CVP) versus 15 months (CVP);
- More patients responded to the combination treatment: overall response rate was 81 per cent (MabThera plus CVP) versus 57 per cent (CVP), and complete response rate quadrupled to 41 per cent (MabThera plus CVP) from 10 per cent (CVP).

"The benefits of MabThera in this patient group are very compelling and we are very pleased that we are able to submit these important data to the European Health Authorities only a few weeks after the results were presented at the annual meeting of the American Society of Hematology in December," said William M. Burns, Head of Roche Pharmaceuticals Division. "Following the European approval of MabThera in relapsed indolent NHL in 1998, this filing may allow us to double the number of indolent NHL patients who have access to this innovative and highly effective drug in the future."

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Non-Hodgkin's lymphoma affects 1.5 million people worldwide who are living with the disease. Indolent NHL, representing about 45% of NHL patients, is a slow developing but serious cancer of the lymphatic system.

About the study

The filing for approval of MabThera in indolent NHL is based on final results from the multi-centre, phase III randomised study, which involved 321 patients from 11 countries* and compared a treatment regimen of MabThera plus CVP chemotherapy with CVP chemotherapy alone. Patients were previously untreated and were diagnosed with advanced stage, indolent (follicular) NHL. Of the 321 patients involved, 159 were randomised into the CVP chemotherapy group and 162 into the MabThera plus CVP chemotherapy treatment group.

About MabThera

MabThera is a therapeutic antibody that binds to a particular protein - the CD20 antigen - on the surface of normal and malignant B-cells. It then recruits the body's natural defences to attack and kill the marked B-cells. Stem cells (B-cell progenitors) in bone marrow lack the CD20 antigen, allowing healthy B-cells to regenerate after treatment and return to normal levels within several months. MabThera is indicated as a single-agent treatment for relapsed or refractory indolent NHL, and received European approval in March 2002 for the treatment of aggressive NHL in combination with CHOP chemotherapy. MabThera is known as Rituxan in the United States, Japan and Canada. More than 300,000 patients have been treated with MabThera worldwide to date. Genentech and Biogen Idec co-market MabThera in the United States, and Roche markets MabThera in the rest of the world, except Japan, where MabThera is co-marketed by Chugai and Zenyaku Kogyo Co. Ltd.

Roche in Oncology

Within the last five years Roche has become the world's leading provider of anti-cancer treatments, supportive care products and diagnostics. Its oncology business includes an unprecedented three marketed products with survival benefit; Herceptin, MabThera and Xeloda, treating a range of malignancies - breast cancer, non-Hodgkin's lymphoma and colorectal cancer. Other key products include NeoRecormon (anaemia in various cancer settings), Bondronat (prevention of skeletal events in breast cancer and bone metastases patients, hypercalcemia of malignancy), Kytril (chemotherapy and radiotherapy-induced nausea and vomiting) and Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma). Roche's cancer medicines generated

* Australia, Belgium, Brazil, Canada, France, Israel, Poland, Portugal, Spain, Switzerland, U.K.

sales of 4.5 billion Swiss francs in the first nine months of 2003.

Roche's products in development also promise survival benefit with Avastin. In a pivotal Phase III study Avastin increased survival duration by 30% when combined with first-line chemotherapy for patients with advanced colorectal cancer.

Roche is developing new tests which will have a significant impact on disease management for cancer patients in the future. With a broad portfolio of tumour markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreas and lung cancer, as well as a range of molecular oncology tests, we will continue to be the leaders in providing cancer focused treatments and diagnostics.

Roche Oncology has four research sites (two in the US, Germany and Japan) and four Headquarter Development sites (two in the US, UK and Switzerland).

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 65,000 people in 150 countries. The Group has alliances and R&D agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

Further information:

www.lymphomacoalition.org

www.health-kiosk.ch