

**Media Release**



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Basel, 4 November, 2003

**European Approval for Bondronat in major additional indication**

**Highly potent oral bisphosphonate set to fill unmet need for prevention of skeletal events in patients with breast cancer and bone metastases**

Roche announced today that the European Commission has approved the use of oral and intravenous Bondronat (ibandronate) for the "prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases."

This indication significantly increases the number of cancer patients who can benefit from Bondronat treatment. The oral formulation is also uniquely positioned to fill an unmet patient need for a highly effective oral bisphosphonate.

"Bondronat is the only bisphosphonate to offer unsurpassed oral and i.v. efficacy and a much improved safety profile compared with currently available i.v. bisphosphonates," said Dr Stefan Manth, Director of Oncology at Roche. "Bondronat is also the only bisphosphonate that has demonstrated significant pain reduction from bone metastases for 2 years, substantially enhancing patients' quality of life," he added.

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The approved dosage of Bondronat for prevention of skeletal metastases in patients with breast cancer and bone metastases is 50 mg daily administered orally at least 30 minutes before food or 6 mg administered intravenously (infusion over 1 hour) every 3 to 4 weeks.

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### **Metastatic Bone Disease**

Metastatic bone disease is the spread of cancerous cells from the original tumour to the bone and generally leads to pain and other clinical consequences, such as skeletal related events, e.g. fractures, compression of the spine, and hypercalcaemia. Bone pain is the predominant reason for patients to seek medical care.

Current therapeutic options for patients suffering from bone metastases include: chemotherapy, hormonal therapy, radiotherapy, analgesics for pain management, surgery and the use of bisphosphonates.

### **About Bondronat**

Bondronat (ibandronate) is a third generation, highly potent nitrogen-containing bisphosphonate. Clinical trials with Bondronat demonstrated significant reduction in skeletal related events and significant rapid and sustained pain reduction throughout a two year study time period. In clinical trials, Bondronat has not been associated with an increase of renal toxicity, with renal adverse event rates similar to placebo. Bondronat has been registered for several years in over 50 countries worldwide for the treatment of hypercalcaemia of malignancy with over 500'000 patients treated to date.

### **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), Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma) and Kytril (chemotherapy and radiotherapy-induced nausea and vomiting). A total of 4.5 billion Swiss francs in oncology product sales were recorded for the first nine months of 2003.

Roche's products in development also promise survival benefit with Avastin. In a recent 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 and is 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 research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

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#### References

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