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Roche

Investor Up

February 27, 200

European Commission Approves Daily Bonviva for the Treatment and Prevention of Post Menopausal Osteoporosis

Key milestone in the development of a drug that aims to provide convenient treatment options for patients and physicians

Roche announced today that they have received approval from the European Commission to market once-daily Bonviva (ibandronate) for the treatment and prevention of post menopausal osteoporosis. A positive opinion for Bonviva was received from the Committee for Proprietary Medicinal Products (CPMP) in October last year and the US Food and Drug Administration (FDA) approved a once-daily formulation of ibandronate (Boniva) in May 2003. The European approval was based on data showing once-daily Bonviva, a new bisphosphonate, provided a 62 percent relative reduction in the incidence of new vertebral fractures with postmenopausal osteoporosis, as well as a favourable tolerability profile.

These approvals mark the first milestone in the progress in developing this medicine. Roche and GSK are continuing to study more convenient dosing regimens that have the potential to offer enhanced patient convenience and compliance. As announced on 13 January, 2004 a recent study (MOBILE) investigating more convenient once-monthly oral treatment of post menopausal osteoporosis with ibandronate demonstrated efficacy and tolerability at least equivalent to the daily regimen.

Once daily Phase III study (BONE, 4411)

In the three-year study, post menopausal women between age 55 and 80 with osteoporosis were treated with either placebo (n= 975) or daily oral ibandronate 2.5mg (n= 977). All women received daily oral calcium (500mg) and vitamin D (400IU). The primary endpoint of the study was the incidence of new vertebral fracture after three years.

The cumulative incidence of new vertebral fractures in the placebo group was 9.6% over 3 years and 4.7% in the 2.5 mg. daily group. Daily oral ibandronate significantly reduced the relative risk of radiologically confirmed vertebral fracture by 62 percent when compared to placebo. Treatment with 2.5mg daily ibandronate also resulted in significant increases in bone mineral density at the lumbar spine and the hip and in decreases in markers of bone turnover to levels similar to those in pre-menopausal women. In this study, ibandronate demonstrated a favourable tolerability profile.

About Osteoporosis

Osteoporosis is a disease characterised by low bone mass and increased fragility and a consequent increase in fracture risk and disability. It is estimated that 1 out of 3 postmenopausal women aged 50 years and older is affected by osteoporosis. One in two women over the age of 50 will have an osteoporosis-related fracture in their lifetime. Approximately 80% of people with osteoporosis are women and 20% are men.

About Bonviva

Bonviva a potent bisphosphonate, has been studied to date in clinical trials involving over 9,000 patients. The ongoing clinical development programme is evaluating monthly oral and intermittent intravenous dosage regimens in women with postmenopausal osteoporosis.

Bonviva is indicated for the treatment and prevention of osteoporosis in postmenopausal women. In postmenopausal women with osteoporosis, Bonviva increases bone mineral density (BMD) and reduces the incidence of vertebral fractures. Bonviva is also indicated for use in postmenopausal women who are at risk of developing osteoporosis and for whom the desired clinical outcome is to maintain bone mass and reduce the risk of vertebral fracture.

About the Roche/GSK Collaboration
In December 2001, Roche and GSK announced that they would co-develop and co-promote Bonviva for the treatment and prevention of postmenopausal osteoporosis in all countries, except Japan. The Roche/GSK collaboration provides expertise and commitment to bring new osteoporosis therapies to market as quickly as possible.

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.

About GlaxoSmithKline
GSK, one of the world's leading research-based pharmaceutical and healthcare companies, is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

Note to editors:
- BMD (Bone mineral density), measured by densitometry, gives an accurate and precise measurement of the amount of bone.
- The name "Bonviva" has been approved in Europe and the name "Boniva" is approved in the US.

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Media Release

Roche

Basel, 27 February 2004

Breakthrough cancer treatment Avastin receives first approval in the US

First anti-angiogenesis treatment approved for cancer

Roche today announced that Genentech has received approval from the US Food and Drug Administration (FDA) for Avastin (bevacizumab, rhuMAb-VEGF), an innovative new cancer drug, to be used with intravenous 5-Fluorouracil-based chemotherapy as treatment for patients with previously untreated metastatic cancer of the colon or rectum (first-line treatment). Genentech will market Avastin in the US and expects it to be shipped within three days.

The US approval is based on data from a pivotal Phase III study in over 900 metastatic colorectal cancer patients which demonstrated that patients treated with Avastin plus IFL chemotherapy had a median survival advantage close to five months, compared to patients on chemotherapy alone (20.3 months versus 15.6 months). This represents the largest improvement in survival time reported in a Phase III clinical study attributable to the addition of a single targeted therapy to conventional chemotherapy.

"The remarkable speed with which the FDA has reviewed and approved Avastin is testimony to the groundbreaking scientific and medical importance this treatment brings to cancer patients," said William M. Burns, Head of Roche Pharmaceuticals Division. "This follows a decision by the FDA in 2003 to designate fast track review status to Avastin. In Switzerland and Canada priority review has already been granted and decisions are pending on requests for priority review in the European Union and Australia. We are dedicated to working closely with regulatory authorities to bring Avastin to patients as quickly as possible, particularly as this is the first treatment of its kind."

Avastin is the first anti-angiogenic therapy – a totally novel approach to the treatment of metastatic colorectal cancer. The drug targets VEGF (Vascular Endothelial Growth Factor), the central mediator of angiogenesis, thus interfering with the blood supply that is critical to the growth of the

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tumour, its spread throughout the body (metastasis) and the effective delivery of chemotherapy within the tumour. As this mechanism may be relevant in a number of malignant tumours, Roche and Genentech are presently investigating the potential clinical benefit of the use of Avastin in a number of other forms of cancer, including non-small cell lung cancer, pancreatic, breast and renal cell carcinoma. Large clinical trials are also underway in patients with colorectal cancer that has not spread (adjuvant therapy).

In 2000, colorectal cancer was the third most commonly reported cancer with 945,000 new cases worldwide. It is estimated that over 50% of people diagnosed with colorectal cancer will die of the disease, and it is the most common cancer in developed countries[1].

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 sales of more than 6 billion Swiss francs in 2003.

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).

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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.health-kiosk.ch
- www.targetVEGF.com

Reference:
1. World Health Organisation. Globocan 2000: Cancer Incidence, Mortality and Prevalence Worldwide. 2000