

Media release



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Basel, 19. September 2005

Roche reselected for inclusion in Dow Jones Sustainability and FTSE4Good Index series

Roche recognised as a leading sustainability-driven company in the healthcare industry

Roche has been reselected as an index component of the Dow Jones Sustainability World Indexes, (DJSI World) and Dow Jones STOXX Sustainability Indexes (DJSI STOXX). Within the healthcare sector Roche is recognized as a leading company in both indexes. In addition, Roche again met the FTSE4Good criteria, so continues to be a member of the FTSE4Good Index series. The selection process involved a thorough assessment of the company's economic, environmental and social performance for inclusion in indexes that track companies that meet globally recognised corporate responsibility standards. The inclusion in these important index series underlines Roche's commitment to responsible business practice and long-term value creation and allows selection of Roche equities into additional sustainability-driven portfolios.

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"I am very pleased that Roche has fulfilled the high criteria set by the Dow Jones family and FTSE4Good series of Sustainability Indexes" said Franz B. Humer, Chairman and CEO of Roche.

"Sustainability is an integral part of our business model: Roche's primary mission is the discovery and development of innovative healthcare solutions that offer society a high medical benefit and ultimately save lives. Along with this, we are looking for new ways to tackle healthcare challenges in providing access to medicines, both in the least developed and the developed countries, so as to ease the global disease burden. Additionally, we are focused on developing our strength as an employer of choice as people are the driving force behind long-term sustainable value creation."

Sustainable development at Roche

Sustainable development has been a core value at Roche ever since the company was founded in 1896. In recent years Roche has extended its internal and external reporting on its efforts in

sustainability, adopting the definition proposed in the 1986 Brundtland Report — namely, that development is sustainable if it meets the needs of the present without compromising the ability of future generations to meet their own needs. In late 2002 the Roche Corporate Sustainability Committee, which reports directly to the Group's Chairman and CEO, was established to assess and coordinate corporate policies and all activities as they relate to sustainable development. In 2004 the first Roche Corporate Sustainability Report, based on the guidelines of the Global Reporting Initiative (GRI), was published as an integral part of the Group's Annual Report.

Dow Jones Sustainability Indexes

Launched in 1999, the Dow Jones Sustainability Indexes are the first global indexes tracking the financial performance of leading sustainability-driven companies worldwide. Based on the cooperation of Dow Jones Indexes, STOXX and SAM, they provide asset managers with reliable and objective benchmarks to manage sustainability portfolios. Currently 52 DJSI licenses are held by asset managers in 14 countries to manage a variety of financial products including active and passive funds, certificates and segregated accounts. In total, these licensees presently manage 2.8 billion euros based on the DJSI.

FTSE4Good Index Series

The FTSE4Good Index Series has been designed to measure the performance of companies that meet globally recognised corporate responsibility standards, and to facilitate investment in those companies. Transparent management and criteria alongside the FTSE brand make FTSE4Good the index of choice for the creation of Socially Responsible Investment products.

Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative 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 is a world leader in Diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004, sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

Media release



Basel, 19 September 2005

Once-monthly oral Bonviva approved for postmenopausal osteoporosis in Europe

Highly effective single monthly tablet a first for any chronic disease

Roche and GlaxoSmithKline (GSK) today announced that European Union marketing authorization has been granted for Bonviva 150mg for the treatment of postmenopausal osteoporosis.

Bonviva (ibandronic acid) is the first and only once-monthly tablet for the treatment of postmenopausal osteoporosis. This announcement follows FDA and Swissmedic approval earlier this year.

Bonviva, a potent and highly effective bisphosphonate¹ is the first ever oral treatment administered as one tablet once a month for any disease. This means patients will only have to take 12 Bonviva tablets a year versus 52 or 365 required with current weekly or daily bisphosphonate treatments. This is particularly important as many patients find osteoporosis therapy inconvenient, which may help to explain why up to two-thirds of patients stop taking their osteoporosis treatment within a year,² foregoing the bone building benefits these drugs can only provide over time.³

Poor adherence has a negative effect on treatment outcomes including lower gains in bone mineral density (BMD),^{4,5} smaller decreases in the rate of bone turnover⁴ and a significantly greater risk of fractures.⁶

William M. Burns, CEO Division Roche Pharma said: "We are very pleased about the European Union marketing authorization for once-monthly Bonviva. We can now offer women with postmenopausal osteoporosis an effective and more convenient regimen which could help them stay on therapy, therefore providing the bone-building benefits they need over time".

Andrew Witty, President of EU Pharma, GSK said: "GSK welcomes this announcement and is delighted to be able to offer healthcare professionals and patients throughout Europe a once monthly treatment option for postmenopausal osteoporosis".

Bonviva, a highly effective bisphosphonate, delivered a reduction in the occurrence of new vertebral fractures of 62% over three years at a 2.5mg daily dose.⁷ Bonviva is also the only nitrogen-containing bisphosphonate that has demonstrated a reduction in vertebral fracture risk using a drug-free interval of more than one day.⁷

European Union marketing authorization for once monthly oral Bonviva is based on 2-year results of the MOBILE (Monthly Oral iBandronate In Ladies) phase III study in 1,609 women with postmenopausal osteoporosis. The study shows the monthly dose was highly effective and well tolerated over two years and is actually statistically superior at increasing bone mineral density (BMD) compared to the daily dose.¹

Bonviva (known in the US as Boniva) 150mg once-monthly oral is indicated for the treatment of postmenopausal osteoporosis in Europe. It is anticipated the UK and Germany will be first to launch the once-monthly formulation in the EU. In the US, once-monthly Boniva 150mg is indicated for the treatment of osteoporosis in postmenopausal women. In the USA and in Europe, Bonviva is co-promoted by GSK.

About MOBILE

MOBILE (Monthly Oral iBandronate In Ladies) is a two-year, randomized, double-blind trial comparing the efficacy and safety of monthly oral doses of ibandronate (100mg on a single day; 100mg as separate 50mg doses on two consecutive days; or 150mg on a single day) versus the oral daily regimen (2.5mg), approved by the FDA and European Commission, in 1,609 women with postmenopausal osteoporosis. The primary endpoint was analysed at 1 year. One year results from MOBILE were recently published in the Journal of Bone and Mineral Research⁴ and full two year results were presented at the Annual European Congress of Rheumatology, Vienna, Austria 8-11 June 2005.¹

About Bonviva

- Bonviva, a potent bisphosphonate, has been studied to date in clinical trials involving over 12,000 patients
- The ongoing clinical development programme is evaluating monthly oral and bi-monthly/quarterly intravenous dosage regimens in women with postmenopausal osteoporosis
- Once-daily Bonviva is indicated for the treatment and prevention of osteoporosis in postmenopausal women by reduction of elevated bone turnover, increasing bone mineral density and reduction of the incidence of vertebral fractures
- Studies specifically designed to demonstrate reductions in non-vertebral or femoral neck fractures have not been conducted with Bonviva

- Bonviva, like other bisphosphonates administered orally, may cause upper gastrointestinal disorders such as dysphagia, oesophagitis and oesophageal or gastric ulcer
- Bonviva (known in the US as Boniva), was approved by the US Food and Drug Administration in March 2005. In the US, Boniva 150mg is indicated for the treatment of osteoporosis in postmenopausal women.

Roche/ GSK collaboration

In December 2001, F. Hoffmann-La Roche (Roche) and GlaxoSmithKline (GSK) announced their plans to 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 bringing new osteoporosis therapies to market as quickly as possible.

About GSK

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. For company information, visit GSK on the World Wide Web at www.gsk.com.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, 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 is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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Additional information

- About postmenopausal osteoporosis: www.roche.com/rnbosteop05e.pdf
- Roche Health-Kiosk, Osteoporosis: www.health-kiosk.ch/start_osteo.htm

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References:

1. Cooper C, Delmas PD, Felsenberg D, Hughes C, Mairon N *et al.* Two-year efficacy and tolerability of once monthly oral ibandronate in postmenopausal osteoporosis: the MOBILE study. Abstract presented at the *Annual European Congress of Rheumatology*, Vienna, Austria 8-11 June 2005.
2. DIN-LINK data, Compufile Ltd, January 2004. NB. Patients are excluded from the analysis at the point where they stop taking therapy altogether or have failed to comply fully.
3. Sebaldt R, Shane L, Pham B, *et al.* Impact of non-compliance and non-persistence with daily bisphosphonates on longer-term effectiveness outcomes in patients with osteoporosis treated in tertiary specialist care. *J Bone Miner Res* 2004;19(Suppl. 1): (Abstract M423).
4. Eastell R *et al.* *Calcif Tissue Int* 2003;72:408 (Abstract P-297)
5. Finigan J *et al.* *Osteoporos Int* 2001;12:S48-S49 (Abstract P110)
6. Caro J *et al.* *Value Health* 2002;5:127
7. Chestnut *et al.* Effects of Oral Ibandronate Administered Daily or Intermittently on Fracture Risk in Postmenopausal Osteoporosis. *Journal of Bone & Mineral Research*, vol. 10: 8, 2004.

Media Release



Basel, 21 September 2005

Tarceva approved in Europe for lung cancer

Thousands of lung cancer patients could now live longer and better if they receive a new cancer treatment – Tarceva – which was approved today across the European Union for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen.

Tarceva (erlonitib) has been shown not only to improve survival by an impressive 42.5% but also to improve disease symptoms and quality of life for patients suffering from NSCLC, the most common form of lung cancer. Today's approval is an important step forward in the fight against this deadly disease – a disease which worldwide claims one life every thirty seconds¹ and currently has very few treatment options.

"Tarceva takes lung cancer treatment a step forward, providing patients, whose treatment options are limited, with not only an extended life but one of better quality," said William M. Burns, CEO Division Roche Pharma. "Its approval across the EU is a continuation of our commitment to ongoing research in the oncology field, with the aim of improving the health and quality of life for people with these devastating diseases."

Taken as an oral, once-daily therapy, Tarceva is the only EGFR-inhibitor to have demonstrated a survival benefit in lung cancer. Currently most lung cancer patients are treated with chemotherapy which can be very debilitating due to its toxic nature. Tarceva works differently to chemotherapy by specifically targeting tumour cells, so avoiding the unpleasant side-effects of chemotherapy.

"Despite being the biggest cancer killer, lung cancer is an often neglected disease," said Dr Giuseppe Giaccone, VU Medical Center, Amsterdam. "Over 50 percent of lung cancer patients in

Europe are not receiving second-line treatment. With the approval of Tarceva, physicians now have a viable alternative to chemotherapy for their patients.”

Approval Based on Compelling Study Results

The EU approval was based on a pivotal Phase III study recently published in the *New England Journal of Medicine* (NEJM).² The study was conducted by the National Cancer Institute of Canada Clinical Trials Group based at Queen's University with the participation of 86 sites from 17 countries around the world. This Phase III study (NCIC-CTG BR.21) involved 731 patients with advanced NSCLC whose cancers had progressed after first- or second-line chemotherapy. The study compared patients receiving Tarceva monotherapy with placebo.

The key study results were:

- Treatment with Tarceva in patients with advanced NSCLC resulted in significantly longer survival compared to placebo, a 42.5% improvement (6.7 months vs. 4.7 months).
- 31% of patients receiving Tarceva were alive at one year compared to 22% in the placebo arm.
- Patients receiving Tarceva had stability or control of their lung cancer-related symptoms such as cough, shortness of breath and pain, for significantly longer.
- Patients also had a superior quality of life and improved physical function compared to those on placebo.
- The benefits of Tarceva were shown in a broad spectrum of patients.

About Tarceva

Tarceva is an investigational small molecule that targets the human epidermal growth factor receptor (HER1) pathway. HER1, also known as EGFR, is a key component of this signalling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva blocks tumour cell growth by inhibiting the tyrosine kinase activity of the HER1 signalling pathway inside the cell.

Tarceva is currently being evaluated in an extensive clinical development programme by a global alliance among OSI Pharmaceuticals, Genentech, and Roche. Chugai is pursuing its development and regulatory approval for the Japanese market. In the United States, Tarceva is marketed by Genentech.

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Additional information

- Roche in Oncology: www.roche.com/pages/downloads/company/pdf/mboncology05e_b.pdf
- Lung cancer: www.lungcancercoalition.org/cancer_facts.html

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1. Global Lung Cancer Coalition. Lung cancer facts: Did you know? www.lungcancercoalition.org/cancer_facts.html. Accessed 12th September 2005.
2. F. Shepherd, J. Rodrigues Pereira, T. Ciuleanu, et al. Erlotinib in Previously Treated Non-Small Cell Lung Cancer, A Trial of the National Cancer Institute of Canada (Clinical Trials Group. N Engl J Med 2005;353:123-32.