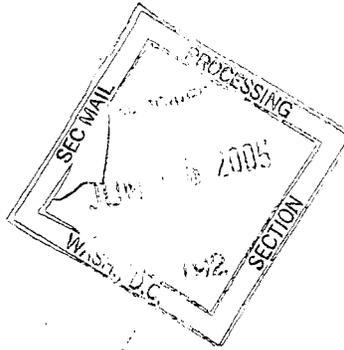


# Media release

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## Roche dedicates world's largest PCR-manufacturing facility in New Jersey

New site for 800 people; investment of more than 150 million US dollars

Roche today dedicated its new Manufacturing Center in Branchburg, New Jersey, USA. The facility is the largest Polymerase Chain Reaction (PCR) manufacturing site in the world and was constructed to manufacture and supply Roche Diagnostics' industry-leading products based on its Nobel-prize winning PCR technology. Roche has spent more than 150 million US dollars for construction of the new structure and renovations to the existing facility. The new plant allows Roche Diagnostics to consolidate the production currently operating in various places in New Jersey to one centralized Branchburg location. The new 26,000 square meter facility will employ up to 800 people, creating approximately 350 new jobs. Foundational work on the new facility began in April 2003.

"It is of utmost importance to have a facility that can respond to the increasing market demand for our PCR products," said Franz B. Humer, Chairman and CEO of the Roche Group. "Within the diagnostics industry, the existing as well as the new PCR tests of Roche Diagnostics like the FDA-cleared AmpliChip CYP450 Test belong to the most innovative products. We anticipate that the consolidation of the manufacturing processes and the integration of the New Jersey activities of Roche Diagnostics into one facility will greatly benefit our business practice as we continue to support the role of PCR technology in changing medicine."

Together with Franz B. Humer and Heino von Prondzynski, CEO Division Roche Diagnostics and Member of Roche's Corporate Executive Committee, further Roche executives, as well as key customers and government representatives, joined the dedication ceremony this morning. It included Mike Ferguson, Congressman from New Jersey, "Kip" Bateman, New Jersey Assemblyman, and Robert Bouwman, Mayor of Branchburg.

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"I applaud Roche's continued commitment to the Branchburg area. To have such a prestigious technology like PCR right here in our backyard is quite an honor. Roche has also truly been a good corporate neighbor since they came to our community back in 1991 in many regards," commented Christopher 'Kip' Bateman, Assemblyman, Somerset County, New Jersey, who is a life-long resident of Branchburg.

In Branchburg, Roche Molecular Diagnostics, a business area of Roche Diagnostics with its headquarters in Pleasanton (California), produces PCR kits for the research, diagnostic and blood screening markets. The diagnostic kits are used for the detection and quantification of infectious diseases such as HIV, Hepatitis and sexually transmitted diseases, as well as for blood screening, including the West Nile Virus kit. The production range also includes reagents for a variety of diagnostic platforms, including microarray technology used in AmpliChip Tests. Overall, Branchburg produces approximately 140,000 kits per month, which are distributed worldwide.

Over the last four years, Roche Diagnostics has seen a 46 percent increase in production volumes of their test kits. As an example, in the blood screening business alone, where Roche Diagnostics' PCR-based tests are used to screen more units of blood worldwide than any other nucleic acid test, their test kits have been used to test more than 100 million blood donations.

#### 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](http://www.roche.com)).

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#### Additional information

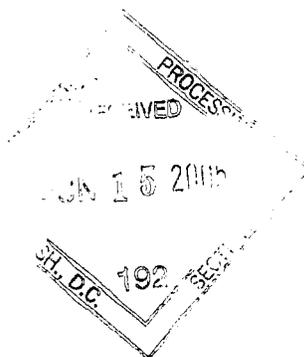
- Polymerase Chain Reaction (PCR): [www.roche.com/pages/facets/pcr\\_e.pdf](http://www.roche.com/pages/facets/pcr_e.pdf)

- Branchburg, New Jersey: [www.branchburg.nj.us](http://www.branchburg.nj.us)
- Roche Diagnostics: [www.roche-diagnostics.com](http://www.roche-diagnostics.com)

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Basel, 9 June 2005

## **New data confirm once-monthly oral treatment for osteoporosis is 'highly effective' over two years**

**MOBILE 2-year results announced today reinforce efficacy, safety and tolerability of Bonviva**

Roche and GlaxoSmithKline (GSK) have announced new results from the landmark MOBILE phase III study. The data, presented for the first time today at the Annual European Congress of Rheumatology (EULAR), confirm Bonviva (ibandronic acid), intended for once-monthly oral treatment for postmenopausal osteoporosis, is highly effective and well tolerated over two years.<sup>1</sup>

William M. Burns, CEO Division Roche Pharma, outlined the implications of these new data: "These new data confirm the one year results presented in 2004 and further strengthen the evidence for the first monthly oral treatment for osteoporosis. Bonviva offers the proven efficacy of a bisphosphonate with the convenience of just 12 tablets a year, which may help patients to stay on therapy longer. This is important because we know that more than 60% of patients who take a once-weekly bisphosphonate stop within a year".<sup>2</sup>

The two year study results show once monthly oral Bonviva is at least as effective as the approved once daily oral Bonviva.<sup>1</sup> The 150mg Bonviva monthly regimen, approved in the US last month, was prospectively demonstrated to be significantly better than the 2.5mg Bonviva daily regimen.<sup>1</sup>

- Lumbar spine bone mineral density (BMD) increased in all groups: 5.3%, 5.6% and 6.6% in the 50+50 mg, 100 mg and 150mg once monthly groups respectively, compared with 5.0% in the daily group. The 150mg regimen continued to be superior to daily Bonviva ( $p < 0.001$ ).<sup>1</sup>
- BMD at all regions of the hip increased for all treatment groups, but increases were most pronounced in the 150mg group: 3.5% and 4.2% , 100 mg and 150mg once monthly groups respectively, compared with 2.5% in the daily group at the total hip.<sup>1</sup>

- Decreases in markers of bone turnover seen during the first year of MOBILE<sup>2,3,4,5</sup> were maintained throughout the second year.<sup>1</sup>
- The majority of participants responded positively to oral ibandronate therapy. In the 150mg once-monthly group over 80% of patients maintained or gained BMD at all sites measured.<sup>1</sup>

These two year data also confirm the good tolerability previously seen at one year:

- Incidence of adverse events with once monthly oral Bonviva was similar to that seen in the daily group.<sup>1</sup>
- No unexpected significant upper gastro-intestinal (GI) safety concerns were identified and there were very few withdrawals due to adverse effects.<sup>1</sup>

Current bisphosphonate therapies are available as daily and weekly dosing formulations. The US Food and Drug Administration approved once-monthly oral Boniva 150 mg in March 2005. In September 2004 Roche and GlaxoSmithKline submitted a Marketing Authorization Application to European regulatory authorities for the once-monthly oral formulation.

#### About MOBILE

MOBILE (Monthly Oral iBANDRONATE In LadIEs) is a two-year, randomized, double-blind trial in 1609 women with postmenopausal osteoporosis 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), previously approved by the FDA and European Commission. The primary endpoint was at 1 year. One year results from MOBILE were presented in 2004 at the 26<sup>th</sup> Annual Meeting of the American Society for Bone Mineral Research, Seattle, USA.<sup>3,4,5,6</sup>

#### About Bonviva

- Bonviva, a potent bisphosphonate, has been studied to date in clinical trials involving over 11,000 patients.
- The ongoing clinical development programme is evaluating monthly oral and bi-monthly/quarterly intravenous dosage regimens in women with postmenopausal osteoporosis.
- Daily Bonviva, indicated for the treatment and prevention of osteoporosis in postmenopausal women, reduces bone turnover, increases bone mineral density and reduces the incidence of vertebral fractures
- The U.S. Food and Drug Administration gave approval for once-monthly Boniva in March 2005. Boniva is not yet approved as a once-monthly formulation in Europe but a marketing

authorization application was submitted in September 2004.

- Bonviva is the only bisphosphonate that has demonstrated a reduction in vertebral fracture risk using a drug-free interval of more than two months.<sup>7</sup>
- Studies specifically designed to demonstrate reductions in non-vertebral or hip fractures have not been conducted with Bonviva.
- Bonviva, like other orally administered bisphosphonates, may cause upper gastrointestinal disorders such as dysphagia, esophagitis and esophageal or gastric ulcer.

#### 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. For further information: [www.roche.com](http://www.roche.com)

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#### Additional information

- About postmenopausal osteoporosis: [www.roche.com/mbosteop05a.pdf](http://www.roche.com/mbosteop05a.pdf)
- Roche Health-Kiosk, Osteoporosis: [www.health-kiosk.ch/start\\_osteop.htm](http://www.health-kiosk.ch/start_osteop.htm)
- GSK website: [www.gsk.com](http://www.gsk.com)

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4. Recker RR, Kendler DL, Adami S, Hughes C, Dumont E, Schimmer RC, Cooper C. Monthly oral ibandronate significantly reduces bone resorption in postmenopausal osteoporosis: 1-year results from MOBILE. Poster F406, presented at 26<sup>th</sup> Annual Meeting of the American Society for Bone Mineral Research, October 1-5, 2004, Seattle, WA.
5. Lewiecki EM, Miller PD, Lorenc R, Hughes C, Bonvoisin B, McClung MR. Monthly oral ibandronate is well tolerated in women with postmenopausal osteoporosis: 1-year results from MOBILE. Poster M429, presented at 26<sup>th</sup> Annual Meeting of the American Society for Bone Mineral Research, October 1-5, 2004, Seattle, WA.
6. Effects of Oral Ibandronate Administered Daily or Intermittently on Fracture Risk in Postmenopausal Osteoporosis. Chestnut *et al.*, *Journal of Bone & Mineral Research*, vol. 10: 8, 2004.
7. International Osteoporosis Foundation.