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Media release

Roche

SUPPL

Once-monthly oral Bonviva approved for postmenopausal osteoporosis in Switzerland

First and only single monthly tablet for any chronic disease

Roche and Glaxo SmithKline today announced that the Swiss health authority Swissmedic has approved Bonviva 150mg (ibandronic acid) for the treatment of postmenopausal osteoporosis. Swiss approval lays the foundation for access to the medicine in more than 70 other countries.

Bonviva is the first and only once-monthly tablet for the treatment of postmenopausal osteoporosis. This announcement marks the first approval of Bonviva outside the United States of America. Bonviva received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) last June and it is expected that European Union marketing authorization will follow later this year.

Bonviva, a potent and highly effective bisphosphonate,[1] 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 required with current weekly bisphosphonate treatments. This is particularly important as almost two-thirds of patients on current treatment stop taking their osteoporosis treatment within a year,[2] foregoing the bone building benefits these drugs can provide over time.[3]

William M. Burns, CEO Division Roche Pharma said, "The approval of once-monthly Bonviva is another example of Roche's commitment to the development of medicines that more closely meet the need of patients. This announcement is significant because we can now offer women with postmenopausal osteoporosis in Switzerland and around the world an effective and more convenient treatment option. This may help them stay on therapy and get the bone-building benefits they need over time."

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The Swiss approval for treatment of osteoporosis in postmenopausal women in order to reduce vertebral fracture is based on 1-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 one year and actually is superior at increasing bone mineral density (BMD) compared to the daily dose,[1] which provides a reduction in the occurrence of new vertebral fractures of 62% over three years [4]. Bonviva is the only bisphoshonate that has demonstrated a reduction in vertebral fracture risk using a drug-free interval of more than one day.[4]

Other oral bisphosphonates, the most frequently prescribed medication for osteoporosis, are available only in daily and weekly dosage forms. The transition of the market from daily to weekly dosing has resulted in better adherence to bisphosphonates, but it remains suboptimal[5]. Poor adherence has a negative effect on treatment outcomes including lower gains in BMD[6,7], smaller decreases in the rate of bone turnover[6] and a significantly greater risk of fractures.[8]

Bonviva (known in the US as Boniva) was approved by the US Food and Drug Administration in March 2005. 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 presented at the 26th Annual Meeting of the American Society for Bone Mineral Research, Seattle, USA [9,10,11,12] 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 9,000 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, esophagitis and esophageal or gastric ulcer

Roche/GSK Collaboration

In December 2001, Hoffmann-La Roche (Roche) and GlaxoSmithKline (GSK) announced their plans to co-develop and co-promote Boniva 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.

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.

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. For further information: www.roche.com

Additional information

- About postmenopausal osteoporosis: www.roche.com/mbosteop05e.pdf
- Roche Health-Kiosk, Osteoporosis: www.health-kiosk.ch/start_osteo.htm

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