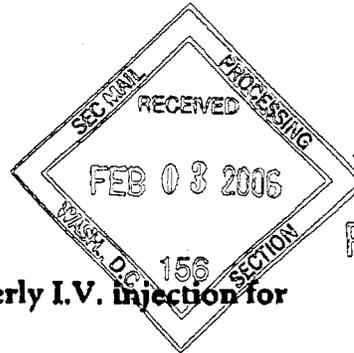


Media Release



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European positive opinion for first quarterly I.V. injection for postmenopausal osteoporosis

New injection could bring benefits of Bonviva to more women

Roche and GlaxoSmithKline (GSK) announce that a new quarterly intravenous (I.V.) injection of the highly-effective osteoporosis medication Bonviva (ibandronic acid) has been recommended for approval in the EU by the Committee for Medicinal Products for Human Use (CHMP). Once approved, this will be the first ever I.V. injection for the treatment of osteoporosis in postmenopausal women available in the EU.

Bonviva is already approved as an effective and well-tolerated¹ once-monthly oral tablet in more than 38 countries. However, for some women with postmenopausal osteoporosis, oral bisphosphonates are not suitable. These women may be unable to take oral bisphosphonate therapy due to another medical condition or because they cannot stay upright for the required length of time.^{*} For these women, Bonviva Injection offers a way to gain the proven bone strengthening benefits of bisphosphonate therapy.

Peter Matton, Roche's Global Head for Bonviva commented: "We know there is a specific group of women who are unable to take oral bisphosphonates. This new quarterly injection of Bonviva allows them to also benefit from this effective class of osteoporosis treatment."

Pierre Delmas, Professor of Medicine and Rheumatology and Director of the INSERM Research Unit in Lyon, said: "Oral bisphosphonates are the most commonly prescribed treatment for postmenopausal osteoporosis. Furthermore, recent studies have shown women prefer Bonviva

^{*} Oral bisphosphonates are taken according to a very strict treatment regime which involves remaining upright and not eating, drinking (except water) or taking other medications for a period of time before and after the therapy has been taken.

once-monthly to once-weekly oral bisphosphonate treatment, finding it more convenient.^{2**} However, for those women who cannot take oral medication, a quarterly injection of Bonviva would provide healthcare professionals with an important, alternative treatment option.”

Bonviva Injection will be presented as a 3mg/3ml solution in a pre-filled syringe and is administered by a healthcare professional as an intravenous injection over 15 - 30 seconds once every three months.

The CHMP positive opinion was based on results from the 2 year DIVA (Dosing IntraVenous Administration) study.³ DIVA investigated the efficacy, safety and tolerability of Bonviva Injection in comparison to the once-daily oral formulation of Bonviva and found it to be highly effective and well-tolerated.³ Previous studies have shown that once-daily oral ibandronate reduced the risk of vertebral fracture in women with postmenopausal osteoporosis by 62% when taken over three years.⁴

About DIVA

DIVA (Dosing IntraVenous Administration) is a multinational, randomised, double-blind, active control multicentre study in more than 1,300 women with postmenopausal osteoporosis aged between 55 and 80 years of age. DIVA compares the safety, efficacy and tolerability of the approved once-daily oral ibandronate 2.5mg regimen with two novel I.V. regimens: 2mg every two months and 3mg every three months, with lumbar spine bone mineral density (BMD) at one year as the primary endpoint.

The two-year findings from the study were presented at the 2005 Annual Scientific Meeting of the American College of Rheumatology, November 12-17 2005.³ For patients who received the 3mg ibandronate every 3 months dosing regimen:

- BMD at the lumbar spine increased more in the I.V. dosing groups than in the daily oral dosing group (6.3 percent vs. 4.8 percent).
- Substantial increases in bone density at the hip (a major non-vertebral site) were also observed, and were also greater in the I.V. group than in the oral daily regimen (3.1 percent vs. 2.2 percent).
- Clinically relevant decreases in bone breakdown (as measured by the biochemical marker of bone resorption, serum CTX) were observed in all treatment groups.

** Who had tried both monthly and weekly treatments

The I.V. regimen was well tolerated. The most common side effects for I.V. ibandronate were bone, muscle or joint pain, influenza-like symptoms and headache.

Regulatory status

The CHMP has issued a positive opinion for Bonviva Injection. This is usually the final step towards approval in Europe. Once approved, Bonviva Injection will be indicated for the treatment of osteoporosis in postmenopausal women, in order to reduce the risk of vertebral fractures. Efficacy on femoral neck fractures has not been established. Boniva Injection was approved by the US Food and Drug Administration on 6th January 2006.

Roche/GSK Collaboration

In December 2001, F 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 a number of major markets, excluding Japan. The Roche/GSK collaboration provides expertise and commitment to bringing new osteoporosis therapies to market as quickly as possible.

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. 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).

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.

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Further information:

-Roche Healthkiosk, Osteoporosis: www.health-kiosk.ch/start_osteopor.htm

-About GSK : www.gsk.com

Roche Group Media Office

Phone: +41-61-688 8888 / e-mail: basel.mediaoffice@roche.com

- Baschi Dürr
- Alexander Klausner
- Daniel Piller (Head of Roche Group Media Office)
- Katja Prowald (Head of Science Communications)
- Martina Rupp

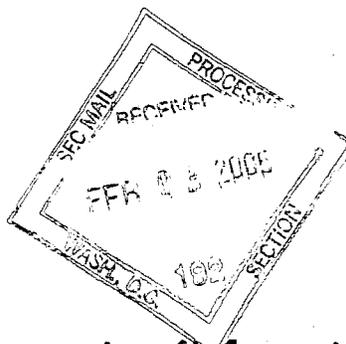
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1. Cooper C, Delmas PD, Felsenberg D, Hughes C, Mairon N et al. Two-year efficacy and tolerability of once monthly oral ibandronate in postmenopausal osteoporosis: the MOBILE study. Abstract presented at the *Annual European Congress of Rheumatology*, Vienna, Austria 8-11 June 2005.
2. BONIVA (ibandronate sodium) INJECTION [prescribing information] Roche Laboratories Inc., Nutley, NJ; 2006.
3. Emkey R, Zaidi M, Lewiecki EM, Burdick A, Mairon N et al. Two-year efficacy and tolerability of intermittent intravenous ibandronate injections in postmenopausal osteoporosis: the DIVA study. Abstract presented at the *Annual Meeting of the American College of Rheumatology*, 12-17 November 2005, San Diego, USA.
4. Chesnut C, Skag A, Christiansen C, Recker R, Stakkestad J et al. Effects of Oral Ibandronate Administered Daily or Intermittently on Fracture Risk in Postmenopausal Osteoporosis. *Journal of Bone & Mineral Research* 2004; 19 (8): 1421-1429

Media Release



Basel, 31 January 2006



Tamiflu gains approval in Europe for prevention of influenza in children aged 1 to 12 years

Roche announced today that its anti-influenza medicine Tamiflu (oseltamivir) has received approval from the European authorities for the prevention of influenza (prophylaxis use) in children aged one to 12 years. An approval for the same indication was received in the United States in December last year.

Tamiflu is already indicated for the treatment of influenza in adults and children aged 1 year and above and for the prevention of influenza in adults and adolescents 13 years and older. Tamiflu is a highly effective influenza drug that works by blocking an enzyme on the surface of the virus which prevents it infecting other cells in the body.

William M. Burns, CEO Division Roche Pharmaceuticals, commented: "The influenza season is just starting in the Northern Hemisphere and Roche plans to make Tamiflu available to prevent influenza in very young children who are particularly vulnerable during an outbreak of the disease. This is particularly helpful in the family setting when one member of the family catches influenza - using Tamiflu for prevention will stop the spread of the disease to other family members."

The application was based on results from a subset of paediatric patients in a clinical study where Tamiflu was used for the management of influenza in households. The study showed that treatment of flu patients with Tamiflu combined with post-exposure prophylaxis of other household members is more effective in preventing secondary spread of influenza infection in the household than treating the patient alone. The protective efficacy of Tamiflu was the same in children aged one to 12 as in the whole population.

Flu's Impact on Children

Influenza is particularly dangerous for the most vulnerable in society and this includes young children and infants. Children younger than two years old are as likely as those over age 65 to be hospitalized because of influenza. It is estimated that children are three times more likely to get sick with the flu – on average, one in 10 adults is affected by influenza annually, compared with one in three children. Therefore, prevention of influenza in children can have a significant impact on the spread of influenza in the household and the whole community.

About Tamiflu

Tamiflu delivers:

- 38 percent reduction in the severity of symptoms
- 67 percent reduction in secondary complications such as bronchitis, pneumonia and sinusitis in otherwise healthy individuals
- 37 percent reduction in the duration of influenza illness
- Tamiflu is shown to provide up to 89 percent overall protective efficacy against clinical influenza in adults and adolescents who had been in close contact with influenza-infected patients

In children, treatment with Tamiflu delivers:

- 36 percent reduction in the severity and duration of influenza symptoms
- 44 percent reduced incidence of associated otitis media as compared to standard care

Pandemic Stockpiling

The World Health Organization (WHO) advises that stockpiling antivirals in advance is presently the only way to ensure that sufficient supplies are available in the event of a pandemic. Roche has been working closely with WHO and national governments to ensure governments are aware of the importance of stockpiling antivirals in the event of a pandemic situation. Roche has received and fulfilled pandemic orders for Tamiflu from around 60 countries worldwide. The magnitude of these orders varies with some countries, France, Finland, Iceland, Ireland, Luxembourg, Netherlands, New Zealand, Norway, Switzerland and UK stockpiling or intending to stockpile adequate Tamiflu to cover 20-40% of their population. To meet this demand Roche has already significantly expanded its Tamiflu production capacity several times, and will continue to take action, both on its own and with several partners, to increase production capacity to assist governments with their pandemic preparedness.

Roche and Gilead

Tamiflu was invented by Gilead Sciences and licensed to Roche in 1996. Roche and Gilead

partnered on clinical development, with Roche leading efforts to produce, register and bring the product to the markets. Under the terms of the companies' agreement, amended in November 2005, Gilead participates with Roche in the consideration of sub-licenses for the pandemic supply of Tamiflu in resource-limited countries. To ensure broader access to Tamiflu for all patients in need, Gilead has agreed to waive its right to full royalty payments for product sold under these sub-licenses.

About Roche

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Additional Information

- Roche Health-Kiosk, Influenza: www.health-kiosk.ch/start_grip.htm
- About Tamiflu: www.roche.com/med_mbtamiflu05e.pdf
- About influenza: www.roche.com/med_mbinfluenza05e.pdf
- WHO: Global influenza programme: www.who.int/csr/disease/influenza/en/
- WHO: Avian flu: www.who.int/mediacentre/factsheets/fs215/en/

Media Relations Contacts

Phone: +41 61 688 88 88 / e-mail: basel.mediaoffice@roche.com

- Baschi Dürr
- Alexander Klausner
- Daniel Piller (Head Roche Group Media Office)
- Katja Prowald (Head Science Communications)
- Martina Rupp