

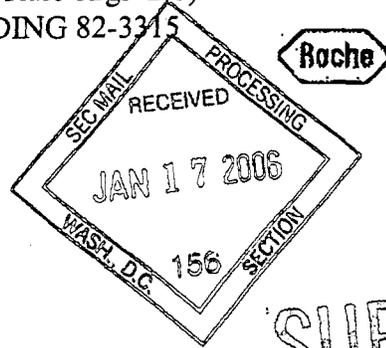
Media Release

Furnished under Rule 12g3-2(b)
ROCHE HOLDING 82-3315



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Basel, 09 January 2006



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FDA approves first quarterly I.V. injection for postmenopausal osteoporosis in US

New injection brings benefits of Boniva to more women

Roche and GlaxoSmithKline (GSK) announce that the U.S. Food and Drug Administration (FDA) has approved a new, quarterly intravenous (I.V.) injection of the potent and highly effective osteoporosis drug Boniva (ibandronic acid). This is the first ever I.V. injection for the treatment of postmenopausal osteoporosis to be approved by the FDA.

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Boniva (known as Bonviva outside the U.S.), is already approved as an effective and well-tolerated¹ once-monthly tablet in 33 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 can not stay upright for the required length of time.* For these women, Boniva Injection offers a way to gain the proven bone strengthening benefits of bisphosphonate therapy.

William M. Burns, CEO Division Roche Pharma commented: "The U.S. approval of quarterly Boniva Injection represents an important new opportunity to bring the bone-strengthening benefits of bisphosphonate therapy to more women. Boniva will now be available as two innovative treatment options that may help patients to stay on therapy."

Gorana Dasic, the US Ibandronate Medical Director at GSK said: "Boniva Injection is the first IV bisphosphonate to be approved for osteoporosis treatment anywhere in the world. It was developed in response to the needs of a specific group of patients and supports our vision to bring

*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.

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bisphosphonate treatment options to more postmenopausal women.”

Boniva Injection is presented as a pre-filled syringe and is administered once every three months by a healthcare professional as a 15 - 30 second injection.

The FDA approval of Boniva Injection was based on one year results from the two year DIVA (Dosing IntraVenous Administration) study.² DIVA investigated the efficacy, safety and tolerability of Boniva Injection in comparison to the once-daily oral formulation of Boniva and found it to be highly effective and well-tolerated.^{2,3} 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

The Marketing Authorisation Application (MAA) for Boniva Injection was submitted to the European Medicines Agency (EMA) in April 2005.

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 efficacy, safety, 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 at one year as the primary endpoint.

- One Year Results²

The FDA approval of Boniva Injection was based on one year results from the DIVA study.² The results showed that the average increase in lumbar spine BMD at one year in patients treated with Boniva Injection (3 mg once every three months) was statistically superior to that in patients treated with the daily oral tablets (4.5 percent vs. 3.5 percent for the two treatments, respectively, $p < 0.001$). The study also showed that patients treated with Boniva Injection had consistently higher BMD increases in the total hip and other skeletal sites (femoral neck and trochanter) than patients treated with oral daily Boniva.²

- Two Year Results³

The two-year findings from the DIVA 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 group than in the daily oral dosing group (6.3 percent vs. 4.8 percent).
- Substantial increases in bone density at the hip (a significant 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 (measured by the biochemical marker of bone resorption, serum CTX) were observed in all treatment groups.

The I.V. regimen was well tolerated.² The most common side effects for I.V. ibandronate reported in a one-year study comparing Boniva Injection and Boniva Tablets 2.5 mg daily were arthralgia, back pain, influenza / influenza-like symptoms, hypertension, abdominal pain and nasopharyngitis.² In some patients, acute phase reaction-like events have been reported, usually only after the first injection. In most cases, no specific treatment was required and symptoms subsided in 24-48 hours. Boniva Injection should not be administered to patients with severe renal impairment.²

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. 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.

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_osteo.htm
- About GSK : www.gsk.com

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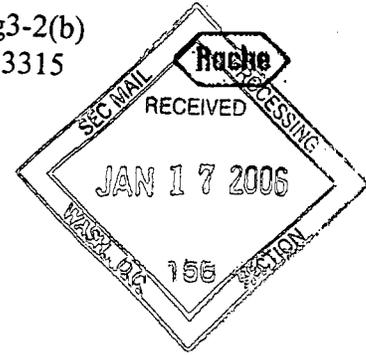
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- Katja Prowald (Head of Science Communications)
- Martina Rupp

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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, Srakkestad J *et al.* Effects of Oral Ibandronate Administered Daily or Intermittently on Fracture Risk in Postmenopausal Osteoporosis. *Journal of Bone & Mineral Research* 2004; 10 (8): 1421-1429

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Basel, 09 January 2006

Roche and Amira Pharmaceuticals announce innovative alliance model

- **Research collaboration for targets in inflammatory diseases**
- **Option for Amira to license specified clinical compounds from Roche**

Swiss healthcare group Roche and San Diego based biotech company Amira Pharmaceuticals today announced a pioneering model for collaboration consisting of a research alliance and an option for Amira to license two clinical stage compounds from Roche.

Under the research collaboration, Roche will use its screening capabilities to investigate three mutually agreed targets in the field of inflammatory diseases. Amira will then utilize its expertise to optimize the lead compounds generated. Roche will have opt-in rights on two of those compounds.

Under a separate licensing option agreement, Amira may license two pre-determined clinical programs from Roche in specific indications in exchange for equity, milestones and royalties.

Amira is a startup company specialized in the field of inflammatory diseases. The firm is funded by investors that include Avalon Ventures, Prospect Ventures and Versant Ventures. The alliance with Amira complements Roche's broad research efforts in inflammation and provides the company with access to innovative external capabilities in a strategic therapeutic area.

"In the past, we referred to a 'win-win' alliance between pharma and biotech partners," said Peter Hug, Roche's Global Head of Pharma Partnering. "Through this new model, we have created a 'win-win-win' deal structure where three main players, Roche, Amira and the venture community, are all benefiting from a joint effort to develop potential new medicines for patients."

"We are very excited to collaborate with Roche. This alliance reinforces the proven pharmaceutical background of Amira's scientists and positions Amira to develop an outstanding

pipeline of novel drug candidates for a broad array of inflammation-based disorders. We look forward to a long and productive partnership," said Peppi Prasit, Chief Scientific Officer of Amira.

Brad Bolzon, Managing Director at Versant Ventures said, "The investors are impressed that a broad, strategic pharma partnership could be established at such an early stage in the development of Amira. Together with financing from Avalon, Prospect and Versant, this deal should enable Amira to rapidly build itself into a strong R&D based company in this important therapeutic area."

Terms of the Agreement

Research collaboration

Roche will screen its compound repository against three targets and will transfer any hits to Amira. In exchange, Roche will have opt-in rights on two of the programs. If Roche exercises its option, Amira could receive up to \$287 million in total event payments, plus royalties.

Amira's option to license Roche clinical programs

Amira will have a one year option to license two of Roche's existing clinical stage programs, in specific indications. Should Amira exercise its option to these programs, Roche may receive a significant percentage of Amira's stock. Additionally, if these two programs meet all development events, Roche could receive up to \$20 million, in addition to royalties.

Inflammatory Research at Roche

Roche has active programs in Inflammation, Autoimmune Disease and Transplant (IAT) research. With its broad development pipeline and existing medicines in IAT (i.e., MabThera, CellCept and Actemra), Roche has the potential to become a leading provider of novel medicines for a range of diseases in this area in the future. The company's IAT research portfolio includes research on small molecules and biologics involving targets such as B cells and inflammatory cytokine responses. Therefore, this alliance with Amira complements Roche's existing research efforts and provides the company with added knowledge and expertise in the area of leukotriene pathways.

About Roche as a Partner

Roche is a valued partner to more than 50 companies worldwide. Over the past two years, Roche has led the pharmaceutical industry in the number of clinical compound deals signed. In 2005, Roche entered into nine partnerships to jointly develop products for optimal patient benefit and value. Partnerships continue to strengthen Roche's positions in oncology, virology, transplantation, and primary care. Roche's partnering culture encourages innovation through a unique pairing of collaboration and autonomy.

About Amira

Founded in 2005 and headquartered in San Diego, Amira Pharmaceuticals is a privately-held biopharmaceutical company, focused on leveraging the deep expertise of an experienced scientific team in the field of inflammatory diseases. The founding team at Amira has over 100 cumulative years of drug discovery experience, which includes the development of marketed drugs for a variety of indications. Its scientific founders include Peppi Prasit, Jilly Evans and John Hutchinson, who have successfully worked together for over a decade. Amira has raised \$9 million to date from investors that include Avalon Ventures (San Diego, CA), Prospect Ventures (Palo Alto, CA) and Versant Ventures (Menlo Park, CA). For more information, visit www.amirapharm.com.

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