

[2003] [AB0536] ORAL MONTHLY IBANDRONATE: RATIONALE AND CLINICAL POTENTIAL IN POSTMENOPAUSAL OSTEOPOROSIS

***J.Y. Reginster<sup>1</sup>, M. McClung<sup>2</sup>, K. Coutant<sup>3</sup>, B. Bonvoisin<sup>3</sup>, R.C. Schimmer<sup>3</sup>, P.D. Delmas<sup>4</sup> 1, University of Liege, Liege, Belgium, 2, Oregon Osteoporosis Center, Portland, United States, 3, F. Hoffmann-La Roche Ltd, Basel, Switzerland, 4Claude Bernard University and INSERM Research Unit 403, Lyon, France***

Postmenopausal osteoporosis (PMO) is a chronic disease that results in substantial morbidity and mortality. Oral daily and weekly bisphosphonates form the current mainstay of treatment for PMO. However, the inconvenience of frequent dosing and need for repeated compliance with stringent dosing recommendations is thought to compromise patient adherence in the long term. Indeed, studies suggest that long-term adherence to current continuously administered bisphosphonate regimens is poor and inferior to that reported in clinical studies (1,2). Thus, novel treatment options that enhance patient convenience through the simplicity of dosing less frequently than once weekly are predicted to promote long-term therapy adherence and optimise patient management in PMO. Ibandronate is a highly potent, nitrogen-containing bisphosphonate with proven efficacy when administered in daily and intermittent regimens in ovariectomised beagle dogs (on/off weeks=2/11) and ovariectomised rats (on/off weeks=1/2, 1/4 and 1/6). Clinically, ibandronate is the first osteoporosis medication proven to offer lasting anti-fracture efficacy (50% reduction in vertebral fracture risk) in regimens with a between-dose interval of >2 months (3). Once monthly ibandronate may offer significant benefits in terms of tolerability (by reducing the potential for oesophageal and gastrointestinal irritation that can result from repeated exposure) and convenience (by having to follow dosing recommendations once monthly vs once daily or weekly). These benefits are predicted to increase long-term adherence relative to current bisphosphonate dosing regimens. The low potential of ibandronate for gastrointestinal (GI) safety concerns, even in patients with a history of GI disturbance, means that the higher doses required to provide sufficient systemic exposure for the efficacy of intermittent regimens can be achieved while ensuring favourable tolerability. Clinical studies are defining the efficacy and tolerability profile of oral monthly ibandronate in PMO.1. Ettinger B, et al. J Managed Care Pharm 1998;488-492; 2. Lombas C, et al. J Bone Miner Res 2000;15:M406; 3. Delmas PD, et al. Osteoporos Int 2002;13(Suppl. 1):S15(Abstract O37)

Osteoporosis Clinical aspects and treatment 2

[Close Window](#)