

Almirall signs a co-promotion agreement with Pfizer to commercialise Conbriza[®] in Spain, a new therapeutic option to treat osteoporosis

- This agreement enables Almirall to reinforce its core business in Spain for the coming years
- Conbriza[®] increases the bone density and reduces the risk of vertebral and non-vertebral fractures in postmenopausal women at increased risk of osteoporotic fracture
- In Spain osteoporosis affects 3 million people of which 2.5 are women

Barcelona, 26 July 2010.- Almirall, the international pharmaceutical company based in Spain, has signed a co-promotion agreement with Pfizer to commercialise Conbriza[®] (bazedoxifene) in Spain, a new medicine for osteoporosis treatment.

With this agreement, Almirall reinforces its core business for the coming years in Spain and enhances its product portfolio in the musculoskeletal therapeutic area in which it has products such as Airtal[®] (aceclofenac), Calmatel[®] (piketoprofen) and Hidroxil[®] (vitaminic complex B12, B6 and B1).

"We are very pleased to have reached this new agreement with Pfizer", said Luciano Conde, Chief Operating Officer at Almirall and added: "With the addition of Conbriza[®] to our product portfolio we are strengthening the musculoskeletal area and at the same time offering an effective solution to a major public health problem, osteoporosis, which has serious health and economic consequences".

Conbriza[®] (bazedoxifene) has recently obtained approval from the Spanish Agency of Medicines (AEMPS) and co-promotion activities will start from September in Spain.

This new medicine will provide an important therapeutic option in the treatment of postmenopausal osteoporosis in women at increased risk of fractures.

Conbriza[®] (bazedoxifene)

Bazedoxifene is the first third generation Selective Estrogen Receptor Modulator (SERM) indicated for the treatment of osteoporosis. SERMs decrease bone resorption and reduce biochemical markers of bone turnover to the premenopausal range. These effects on bone remodelling lead to an increase in bone mineral density (BMD), which in turn contributes to a reduction in the risk of fractures.

Bazedoxifene has obtained the approval in Spain based on the efficacy and safety data proven in two multicentre clinical studies developed on about 10,000 postmenopausal osteoporotic women^{1,2}. The first study was a two-year study on prevention of osteoporosis and the second a three-year study of treatment of osteoporosis that showed an incidence reduction of new vertebral and non-vertebral fractures (in a subgroup of patients at high risk). This superiority in the efficacy endpoint, preventing the appearance of new fractures, has been evaluated and confirmed against placebo, with 42% lower relative risk of vertebral fractures and 50% fewer non-vertebral fractures than placebo.

¹ **Miller et al.** Effects of Bazedoxifene on BMD and bone turnover in Postmenopausal Women: 2-Year results of a randomized, double-blind, placebo and active-controlled study, *JBMR*, 2008, Apr, 23(4): 525-535.

² **Silverman et al.** Efficacy of Bazedoxifene in Reducing New Vertebral Fracture Risk in Postmenopausal Women with Osteoporosis: Results from a 3-Year, randomized, placebo and active controlled clinical trial. *JBMR*, 2008, Dec, 23 (12): 1923-1934.

In the phase III safety studies compared to placebo performed for over five years on 4,216 postmenopausal women, bazedoxifene showed a lower rate of occurrence of endometrial carcinoma and a neutral effect on breast tissue³.

Efficacy data on relative risk reduction of occurrence of vertebral and non-vertebral fractures, and its security at endometrial and breast level, has allowed bazedoxifene to become the leading representative of third generation Selective Estrogen Receptor Modulator (SERM) and a promising therapeutic innovation for women with postmenopausal osteoporosis at increased risk of fractures⁴.

About osteoporosis⁵

Osteoporosis is a major public health problem given its serious health and economic consequences. In Spain it affects 3 million people, of which 2.5 million are women. Despite the high prevalence, less than 30% of patients are diagnosed and less than 10% receive treatment.

Osteoporosis is the most common bone disease characterised by reduced bone mass and microarchitectural deterioration of bone tissue with a consequent increase in bone fragility and fracture risk.

The main objective of the prevention and treatment of osteoporosis has always been to reduce the risk of fracture, leading to an increase in quality of life of patients. The prevalence of osteoporosis increases progressively from 60 years of age and is higher in women at an approximate ratio of 3-4 for each man.

Worldwide, osteoporosis was the cause of approximately 9 million fractures in 2000 in 50-year-old men and women, according to WHO data. Women were most affected, as they suffered 61% of vertebral fractures, 70% of hip fractures, 80% of the forearm and 75% of the humerus. In fact, studies estimate that more than half Caucasian women aged 50 will suffer an osteoporotic fracture during their lives, highlighting the seriousness of the problem.

About Almirall

Almirall is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, it researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing.

The therapeutic areas on which Almirall focuses its research resources are related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), rheumatoid arthritis, multiple sclerosis, psoriasis and other dermatological conditions.

Almirall's products are currently present in over 70 countries while it has direct presence in Europe and Latin America through 11 affiliates.

For further information please visit the website at: www.almirall.com

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³ **Palacios et al.** Endometrial and breast safety of bazedoxifene in postmenopausal women with osteoporosis: findings from a 5-year, randomized, placebo-controlled, phase 3 trial. Abstract submitted for IOF WCO-ECCEO 2010, May, Abs. 53462.

⁴ **Taylor HS.** Approaching the ideal selective estrogen receptor modulator for the prevention and treatment of postmenopausal osteoporosis. *Fomulary* 2010, Feb 45: 52-61.

⁵ Source: ©GEIOS. Study and Research Group of the Spanish Society of Orthopaedic Surgery and Traumatology. January 2010. Published by: Multimédica Proyectos, S.L.