

MEDICAL NEWS RELEASE

Issued on behalf of Servier Laboratories Ltd

Protelos[®] is the first treatment to reduce the risk of vertebral and non-vertebral fractures in elderly women (over 80 years) with osteoporosis

Vienna, 17th March 2006: Protelos[®] (strontium ranelate) is the first anti-osteoporotic treatment to demonstrate an early and sustained reduction for vertebral and non-vertebral fractures in women over 80 years of age. Results announced last night at the Sixth **E**uropean **C**ongress on **C**linical and **E**conomic Aspects of **O**steoporosis and **O**steoarthritis (ECCEO), from trials of 1,488 women, show that even in the very elderly, it is not too late to effectively treat the disease.

A pre-planned analysis based on pooled data from two international studies Spinal Osteoporosis Therapeutic Intervention (SOTI) and Treatment of Peripheral Osteoporosis (TROPOS) included women aged 80 – 100 years. Results showed that during the first year of treatment Protelos reduced the risk of vertebral fracture by 59% (RR=0.41; 95%CI[0.22;0.75], p=0.002), clinical vertebral fractures by 37% (RR=0.63; 95%CI[0.44;0.91], p=0.012) and non-vertebral fractures by 41% (RR=0.59; 95%CI[0.37;0.95], p=0.027), compared to placebo. The vertebral and non-vertebral fracture risk reduction was maintained over three years.¹

Osteoporotic women over the age of 80 are an under diagnosed and under treated patient group, despite their contribution of over 30% of all fragility fractures and 60% of hip fractures.² A fracture at any site can cause catastrophic events resulting in pain, disability, loss of confidence and an altered lifestyle. In the case of hip fractures, patients have a 2-10 fold increase in the risk of mortality in the first 12 months following a fracture.³ Up to half of all hip fracture patients will lose the ability to live independently,⁴ making evidence for treating patients over the age of 80 extremely important.

Commenting on the results, the study co-ordinator Professor Tim Spector, Consultant Rheumatologist said, "Despite the plethora of studies into the effects of osteoporosis treatments on fracture reduction, few studies have focused on the elderly. Protelos is the only anti-osteoporotic drug to have data showing sustained and significant benefits in both vertebral and non-vertebral fractures".

The number of elderly individuals with osteoporosis will rise dramatically in the coming years, as this group of women constitute the fastest growing segment of the population.⁵ Women can expect to live to the age of 85 on average and this is predicted to increase by a further three years by 2021⁶. The consequences of inappropriate treatment in the elderly should not be underestimated.

Protelos was launched in the UK in November 2004 and is licensed for the treatment of postmenopausal osteoporosis, to reduce the risk of vertebral and hip fractures. Protelos is the only osteoporosis drug to simultaneously increase bone formation and decrease bone resorption.

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Editor's notes

- Osteoporosis is defined as a progressive systemic skeletal disease characterised by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture.⁷
- The clinical phase III, double blind placebo controlled SOTI and TROPOS studies were conducted in 75 European and Australian centres.
- Protelos is a 2g sachet of tasteless powder to be dissolved in a glass of water, taken once daily, preferably at bedtime, at least two hours after eating.
- Protelos is currently being reviewed by the National Institute for Clinical Excellence (NICE) in England and Wales, with final guidance expected in autumn 2006.
- Protelos is manufactured by Servier Laboratories Ltd, an independently owned pharmaceutical company based in France. Servier has over 16,000 employees worldwide, including 2,500 in research and development.

References

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