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***MEDICAL NEWS RELEASE***

Issued on behalf of Servier Laboratories Ltd

**Protelos<sup>®</sup> Demonstrates Unique Long-term Osteoporotic Fracture Reduction**

**Vienna 17<sup>th</sup> March 2006:** The results of two landmark studies announced today at the Sixth European Congress on Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ECCEO), confirms the evidence based, long-term efficacy of Protelos (strontium ranelate) for the reduction of nonvertebral and vertebral osteoporotic fractures over five years.<sup>1</sup> This is the first time an anti-osteoporotic treatment has demonstrated fracture reduction efficacy after five years of treatment.

Protelos is an anti-osteoporotic treatment with an innovative mode of action, simultaneously increasing bone formation whilst decreasing bone resorption. The results of the **S**pinal **O**steoporosis **T**herapeutic **I**ntervention (SOTI) trial of 1649 postmenopausal women with osteoporosis demonstrated that Protelos significantly reduced the long-term risk of developing a new vertebral fracture by 33%, in the intention-to-treat population over four years of treatment (RR=0.67; 95%CI[0.55;0.81],Cox model: p<0.001). This long-term efficacy was confirmed by five-year results from the **T**reatment **O**f **P**eripheral **O**steoporosis (TROPOS) study of 5091 osteoporotic women, which found that Protelos reduced the risk of vertebral fractures by 24% (RR=0.76; 95% CI[0.65;0.87] Cox model: p<0.001) and caused a 15% reduction in nonvertebral fractures (RR=0.85; 95% CI[0.77;0.99] Cox model: p=0.03) in the intention-to-treat populations.<sup>1</sup>

*Commenting on the results, Professor Tim Spector, Consultant Rheumatologist said, "This five-year fracture reduction data is really exciting, as it is the first time any anti-osteoporotic treatment has demonstrated long-term benefit, over such a range of fractures. This data provides excellent support for the long-term use of Protelos."*

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 anti-osteoporotic treatment to simultaneously increase bone formation and decrease bone resorption. It is administered as a 2g sachet of tasteless powder to be dissolved in a glass of water, which should be taken once daily, preferably at bedtime, and at least two hours after eating.

It has been estimated that in England and Wales, approximately 180,000 symptomatic osteoporotic fractures occur each year, with around 50% of these fractures occurring in women over the age of 75 years.<sup>2</sup> The combined social care and medical costs for treating osteoporotic fractures is estimated to be between £1.5 and £1.8 billion annually in the UK.<sup>2</sup>

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## Editor's notes

- This new anti-fracture data is a continuation of the previously published three year SOTI and TROPOS trial data
- Osteoporosis is a progressive bone disease characterised by a loss of bone density and deterioration of the bone structure. This results in increased bone fragility and susceptibility to fracture.<sup>3</sup> At least one in three adult women and one in five adult men aged 50 and over will sustain one or more vertebral, hip or other fractures.<sup>4</sup>
- The clinical phase III, double blind placebo controlled SOTI and TROPOS studies were conducted in 75 European and Australian centres.
- Protelos is currently being reviewed by the National Institute for Clinical Excellence (NICE) in England and Wales, with final guidance expected in autumn 2006.
- Servier Laboratories is an independently owned pharmaceutical company based in France. Servier has over 16,000 employees worldwide including 2,500 in research and development.
- Servier's commitment to research has resulted in one of the most active product pipelines in the industry. The Company invests over 25% of annual turnover into research, a figure double the industry average.
- Servier's contribution to improving the management of disease in the UK remains a key priority, with products in the osteoporosis, cardiovascular and diabetes therapy areas.

## References

1. Reginster JY. et al. Strontium ranelate: An anti-osteoporotic treatment demonstrated vertebral and nonvertebral anti fracture efficacy over five years in postmenopausal women. Presented at: Sixth European Congress on Clinical and Economic Aspects of Osteoporosis and Osteoarthritis. March 2006
2. National Institute for Clinical Excellence. Technology Appraisal Guidance 87. Issued January 2005.
3. Royal College of Physicians, Bone and Tooth Society of Great Britain. *Osteoporosis: Clinical guidelines for prevention and treatment. Update on pharmacological interventions and an algorithm for management*. London: RCP, 2001: [www.rcplondon.ac.uk/pubs/wp\\_oste\\_update.htm](http://www.rcplondon.ac.uk/pubs/wp_oste_update.htm) (last accessed 17 October 2003).
4. National Osteoporosis Society website. *What is Osteoporosis?* Available at: [www.nos.org.uk](http://www.nos.org.uk) (Last accessed January 2006).

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