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## Cardiovascular risks of HRT confirmed

**Monday 1st of July 2002 8:00**

### Cardiovascular risks of HRT confirmed

*Treatment with combined estrogen/progestin doubles the risk of VTE in post-menopausal women and for obese women the risk is even higher, a recent study showed. However millions of women no longer taking HRT remain at risk of osteoporosis, which presents a huge market opportunity for non-hormonal classes in treating and preventing osteoporosis.*

The final data on the incidence of venous thromboembolism (VTE) in the Womens Health Initiative Estrogen Plus Progestin clinical trial was published this month in the Journal of the American Medical Association.

The aim of the trial, part of a 15 year program to investigate morbidity and mortality in women that started in 1991, was to determine whether hormone replacement therapy with combined estrogen and progestin may offer some cardioprotection to post-menopausal women. However the trial was stopped prematurely in July 2002 when investigators found that treatment with the combination actually resulted in a significant increase in venous thromboembolism (VTE).

#### *Landmark study*

The final results of this study, which randomized 16,608 women aged 50-79 to active treatment with Prempro (0.625 mg conjugated equine estrogen plus 2.5 mg medroxyprogesterone acetate daily) or placebo, showed that overall, women receiving treatment had double the risk of VTE compared to women on placebo. The risk increased with age: compared to women aged 50-59, the risk of VTE in women aged 60-69 and 70-79 was 2.03 and 3.72 times higher, respectively.

Researchers also found that obesity was a major contributor to risk: obese women on active treatment have a 6-fold higher risk of VTE than non-obese women on placebo. Cigarette smoking, cholesterol level or use of oral contraceptives did not influence the risk of VTE.

Publication of the initial results in 2002 led to millions of women discontinuing hormone replacement therapy and a \$600 million uplift in the sales of non-HRT classes used to prevent osteoporosis. Datamonitor estimates that one in three women who stopped HRT have not been prescribed an alternative therapy and remain at high risk of fracture in later life due to osteoporosis. This population should represent a key target for manufacturers of non-HRT osteoporosis drugs that do not increase the risk of VTE or breast cancer.

#### *New treatments in development*

R&D activity within the HRT sector has been targeted to satisfy the more restrictive recommendations for hormone therapy in the postmenopausal population since the WHI. Major players in the market are developing low dose formulations and investing in transdermal delivery methods. This includes Wyeth's two new low dose additions to both the Premarin and Prempro lines launched over 2003 and 2004, and Warner Chilcott's FemHRT LO currently awaiting FDA approval, as well as Berlex's recently launched low dose Menostar patch.

Non-HRT osteoporosis drugs include the bisphosphonates Fosamax (Merck) and Actonel (Procter & Gamble/Aventis), selective estrogen receptor modulators (SERMs) such as Lilly's Evista, calcitonins such as Miacalcin (Novartis) and Lilly's other osteoporosis product Forteo, a parathyroid hormone derivative. Datamonitor analysis has shown that, in recent years, the calcitonins have been slowly losing market share to the bisphosphonates and SERMs and will continue to do so until 2014.

Evista is particularly well positioned as a non-hormonal alternative to HRT in preventing bone loss. Further possible advantages of the drug are being investigated in trials for breast cancer prevention, and primary research suggests that Evista is already being prescribed under the assumption of its efficacy in this indication.

*Related research:*

- *Commercial Insight: Osteoporosis and HRT - Novel Osteoporosis Drugs Counter Generic Threat While HRT Players Regroup and Move Forward*
- *Stakeholder Insight: Osteoporosis - Poor Disease Awareness and Patient Identification Hinder Market Growth*
- *PharmaVitae 2004: Wyeth Global Analysis*

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