



# Bone Medical

ASX/MEDIA RELEASE

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## **BONE MEDICAL COMPLETES *PERTHOXAL*<sup>™</sup> OSTEOPOROSIS TRIAL**

Bone Medical Ltd (ASX: BNE) (Bone Medical) announced today the completion of a Phase I trial of its oral parathyroid hormone (PTH) product *Perthoxal*<sup>™</sup> under development for the treatment of osteoporosis.

The trial involving 18 post-menopausal women was conducted at the Clinical Trials Centre at St Vincent's Hospital in Sydney. The final report is expected to be completed by October.

The primary aim of the study is to assess the safety and tolerability of *Perthoxal*<sup>™</sup> oral PTH in two different formulations. A secondary aim is to determine whether *Perthoxal*<sup>™</sup> oral PTH has the desired result of increasing the concentration of calcium in the bloodstream and the levels of PTH in the blood.

Each participant received a placebo and two of the possible three PTH forms – two *Perthoxal* test formulations and Eli Lilly's FORTEO®, an injectable dosage form of PTH as a positive control. For each subject, blood samples were taken over a 10-hour post-treatment period for the subsequent measurement of calcium, PTH and a biological marker of bone turnover.

"Our goal is to develop a patient-friendly dosage form of PTH treatment which could replace an injectable product that requires daily dosing. We believe that *Perthoxal*<sup>™</sup> as an oral capsule could compete directly with injectable forms of PTH and also has the potential to compete with or be complimentary to the US\$4 billion bisphosphonate market," said Michael Redman, Chief Executive Officer of Bone Medical.

*Perthoxal*<sup>™</sup> oral calcitonin is the second product in Bone Medical's portfolio to commence human clinical testing, following a successful first-in-human study using *Capsitonin*<sup>™</sup> oral calcitonin last year.

### **Parathyroid Hormone**

Both *Perthoxal* and FORTEO® contain teriparatide, a recombinant form of the 34 amino-terminal amino acids of human parathyroid hormone. FORTEO® was approved by the US FDA in November 2002 for the treatment of osteoporosis. Teriparatide was the first drug approved by the FDA to stimulate bone formation. Other marketed osteoporosis therapies include bisphosphonates and selective oestrogen-receptor modulators, which are believed to inhibit bone resorption but do not induce bone formation.

### **Osteoporosis**

According to the World Health Organization, osteoporosis is the second leading health care problem in the world, affecting an estimated 200 million women worldwide. It is predicted that the incidence of osteoporotic fractures will double

during the next 50 years resulting in the worldwide cost burden of osteoporosis (for all ages) to increase to USD131.5 billion by 2050.

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**About Bone Medical Limited**

Bone Medical Limited is an international biopharmaceutical development company positioned to exploit the growing market in the treatment of bone disease particularly in osteoporosis and arthritis. Bone has a portfolio of biopharmaceutical development projects for the treatment of bone disease including,

Osteoporosis

- *Capsitonin*<sup>™</sup> oral calcitonin
- *Perthoxal*<sup>™</sup> oral parathyroid hormone
- bone cell regulators BN005/BN008

Arthritis

- TNF regulators BN006
- joint protection & collagen tolerance BN007