

# Bone Medical

## ASX/MEDIA RELEASE

### **Commencement of Human Clinical Study for an Oral Treatment for Osteoporosis**

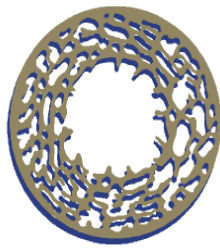
**02 July 2014:** Bone Medical Ltd (Bone Medical or the Company) is pleased to announce that it has commenced the planned human clinical study as announced to the ASX on 4 April 2014.

The study will compare Bone Medical's potential oral treatment for osteoporosis, CaPTHymone™, against a commercially available injectable osteoporosis treatment, Forteo®.

Parathyroid hormone ("PTH") is a naturally-occurring hormone that plays an important role in regulating bone formation. Bone Medical is developing an orally-delivered PTH formulation for the treatment of osteoporosis. An injectable PTH formulation, Forteo® is already approved and on the market for the treatment of osteoporosis. Forteo® reported sales in excess of US\$1.2 billion in 2013. However, patient acceptance of this product is limited by the fact that it needs to be injected, and it is expected that an oral form will lead to a significant increase in market size.

The human clinical trial will primarily assess and compare PTH blood levels based on administering different dosage strengths of Bone Medical's oral PTH formulation versus the injectable Forteo® PTH formulation. Each patient will receive three different oral PTH dosage strengths, Forteo®, or placebo in random order. The trial is an extension of a similar study conducted in 2012-13 using lower oral PTH doses that showed evidence of biological activity, confirming absorption after oral administration.

A separate earlier study demonstrated the presence of PTH peptide fragments in the bloodstream after oral administration of the CaPTHymone™ formulation. The current study's aim is to confirm this finding, thus paving the way for further studies in the clinical development programme, looking at long-term change in bone growth, which will engage early industry partnering interest. If, at the same time, intact PTH peptides are detected in the blood, this could permit an even faster, simplified development plan for CaPTHymone™.



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"It is a long-unfulfilled goal of the pharmaceutical industry to be able to give treatments like PTH by mouth instead of by injection" said Rob Towner, Bone Medical Chairman. "If the current study is positive, our oral PTH formulation could dramatically increase the ease of use of PTH in the growing population of osteoporosis patients."

Results from the study are expected in approximately three months.

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**About Bone Medical Limited**

Bone Medical Limited is an international biopharmaceutical company focused on developing significant new products for the growing market in the treatment of bone diseases like osteoarthritis, rheumatoid arthritis, and osteoporosis.