



ASX/MEDIA RELEASE

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BONE ANNOUNCES HUMAN CLINICAL TRIALS FOR BONE-BUILDING HORMONE

Biopharmaceutical development company Bone Medical Limited (**ASX: BNE**) is pleased to announce it has received clearance to commence human clinical trials of its oral parathyroid hormone (PTH), BN003. The study will be conducted at the Clinical Trial Centre of Sydney's St Vincent's Hospital.

The BN003 oral PTH project is Bone Medical's second project to progress to human clinical studies and represents another critical milestone achieved by the Company.

The product is designed to allow osteoporosis patients to take their medicine orally in pill form rather than through injection, currently the only available form of parathyroid hormone.

Bone Medical's Chief Operating Officer John Fitzgerald said, "With the commencement of this study, Bone Medical will have two products in human clinical development, a third in pre-clinical development and four others at various stages of development."

"Each of these products address unmet therapeutic needs in large global markets," he said.

"We believe this makes us one of the most advanced biopharmaceutical companies in Australia."

Currently, injectable PTH is the only product in the world to be indicated by the US Food & Drug Administration (FDA) to build bone. Injectable PTH is predicted by some pharmaceutical analysts to sell US\$450 million per annum by 2007.

"As osteoporosis is a condition of bone thinning, the ability to safely build normal bone has been the 'Holy Grail' for therapies in this area," said Mr Fitzgerald. "If oral PTH were to replace the injected version, it has the potential to significantly expand the market through greater patient acceptance."

Bone Medical has appointed leading authority Professor Philip Sambrook as Chief Investigator of the study as a result of his expertise in the area of osteoporosis. Dr Sambrook is Director of the Institute of Bone and Joint Research and a Director of Osteoporosis Australia. He will be assisted by Professor Richard Day, Director of Clinical Pharmacology and Toxicology at St Vincent's Hospital.

Three pre-clinical studies using BN003 oral PTH have been completed by a major international pharmaceutical company under a confidential testing agreement. These studies showed that the formulation BN003 can deliver PTH into the bloodstream of the animals tested and resulted in increased blood calcium levels.

The St Vincent's Hospital study will involve healthy post-menopausal women with safety and tolerability as the primary outcomes, and is due to commence in February with results expected in the second quarter of 2005.

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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*TM oral calcitonin
- oral parathyroid hormone BN003
- combination therapy BN004
- bone cell regulators BN005/BN008

Arthritis

- TNF regulators BN006
- joint protection & collagen tolerance BN007

About St Vincent's Clinical Trials Centre

The St Vincent's Clinical Trials Centre provides inpatient, and ambulatory services to undertake Phase I-III trials. Underpinned by a nationally recognised Research Ethics Committee, Clinical Trial Pharmacy, and Central Pathology Service, studies are conducted under Australia's Clinical Trial Notification scheme that divests responsibility to approve studies to the local Institution allowing efficient and timely review, approval and conduct of studies.

About Oral Parathyroid Hormone BN003 (Osteoporosis)

Parathyroid hormone (PTH) is one of the principal controlling agents for the maintenance of normal calcium levels in the blood.

BN003 oral PTH contains no new chemical entities and uses the same delivery system as Bone's *Capsitonin*TM oral calcitonin. The Company believes the successful proof of concept study for *Capsitonin* oral calcitonin augurs well for the oral PTH program.

Bone has been awarded a A\$250,000 grant from the Australian Federal Government's Biotechnology Innovation Fund (BIF), the maximum amount available under the scheme, to assist in the completion of pre-clinical testing and commence human clinical development. The BIF is a competitive, merit-based program and the award of this funding provides further independent validation of our technology and represents another milestone achievement for the company.