

## **ASX/MEDIA RELEASE**

# Continuation of Studies for Bone Medical's breakthrough Rheumatoid Arthritis treatment

**19 June 2014:** Bone Medical Ltd (Bone Medical or the Company) is pleased to announce that it has commenced further studies on its potential breakthrough rheumatoid arthritis treatment, BN006.

These studies are part of the original scope of work announced under the Company's recapitalization and offer Bone Medical significant growth opportunities.

Studies carried-out in 2013 show that in a commonly-used rheumatoid arthritis animal model BN006 is as effective as the highest selling treatment for rheumatoid arthritis currently on the market, Humira®. In 2013, global sales of Humira reached US\$10.6bn.

Rob Towner, Chairman of Bone Medical, stated: "The 2013 results provided preclinical proof of concept for BN006 and so we are very excited to continue studies to progress this breakthrough future therapy for rheumatoid arthritis. BN006 has the potential to be a far superior treatment as it has shown to achieve a therapeutic effect without as much immune-system suppression as other treatments, thereby reducing the risk of infection to patients as well as being a more patient-friendly orally-deliverable treatment."

The studies carried-out in 2013 showed that BN006 was efficacious even at the lowest dose tested. In the current experiments Bone Medical will test a lower range of dosages with the aim of confirming the full breadth of BN006's dose response.

The same 2013 studies also demonstrated that BN006, when taken orally, can be absorbed in the bloodstream at levels correlating with its anti-inflammatory efficacy. The current experiment will more fully characterise BN006's profile after oral delivery. The current market leader Humira® is given by injection.

The current experiments are expected to be completed by the end of July 2014 with results anticipated in the month following. Positive results from these studies will advance BN006 nearer to the commencement of human clinical trials, a major milestone for this product program.



## **Update on other Bone Medical programmes**

A collaboration with the prestigious William Harvey Research Institute in London is underway, with an investigation into BN006's mechanism of action. This work will throw further light on the nature of the receptor on the macrophage to which BN006 binds.

The Company's latest clinical study for its oral PTH (parathyroid hormone) product for the treatment of osteoporosis is expected to commence by the end of June 2014. This will be conducted under the auspices of Q-Pharm Pty Ltd in Queensland, one of the foremost clinical trial research organizations in Australia.

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#### **About BN006** (oral TNF-alpha down-regulator for rheumatoid arthritis)

Tumour necrosis factor (TNF) has been implicated in inflammatory diseases such as rheumatoid arthritis. Antibody-based products that reduce the level of TNF are some of the highest-selling products worldwide. However, these anti-TNF antibody products suppress TNF systemically, which can also suppress the immune system's normal functions, and are available only as injectable biological products.

BN006 is a novel peptide compound created using Bone Medical's licensed Mozaic<sup>TM</sup> peptide discovery and companion Lexcicon<sup>TM</sup> technology. Its mechanism of action relates to prevention of secretion of TNF by macrophages, rather than mopping up of TNF by antibodies after it is produced. BN006 appears to leave lymphocytes unaffected, so that the normal immune functions which these cells perform (resistance to pathogens, cancer surveillance) via the intermediary of TNF, can continue unimpaired.



#### **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.

The Company's product pipeline includes:

- Clinical-stage programs for the oral delivery of two well-established peptides which have historically been limited to nasal or injectable delivery
  - o CaPTHymone<sup>™</sup> (oral parathyroid hormone) for osteoporosis
  - Capsitonin™ (oral calcitonin) for osteoarthritis pain
- Novel, potential breakthrough preclinical-stage compounds
  - BN006 selective, oral TNF-alpha down-regulator for rheumatoid arthritis (RA)
  - BN007 collagen tolerance & joint protection agent for RA
  - o BN005 & BN008 bone cell regulation for osteoporosis