



Bone Medical

ASX/MEDIA RELEASE

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BONE MEDICAL'S PROGRESS WITH ARTHRITIS DRUG CANDIDATE

Bone Medical Limited (ASX: BNE) today announced the release of data demonstrating its drug candidate, BN006, is effective in inhibiting expression of tumour necrosis factor (TNF) in human cells. TNF is known to contribute to the debilitating symptoms of rheumatoid arthritis. Importantly, BN006 was effective against a relevant human cell line and caused dose-dependent inhibition of TNF release of up to 100 per cent.

This data support earlier pre-clinical testing that showed BN006 to be effective in inhibiting the release of TNF in mouse cell lines and in a rat animal model.

This study involved growing a human macrophage cell line in the laboratory, adding different concentrations of BN006 to the growth medium of the cells and measuring the genetic signals for the production of TNF and signs of toxicity to the cells. At higher concentrations, BN006 was able to block TNF release completely. At lower concentrations, TNF was partially inhibited depending on the concentration of BN006.

“Bone commenced this series of studies in response to feedback from initial discussions with international pharmaceutical companies who wanted to understand the mechanism of action,” said Mr Michael Redman, Chief Executive Officer of Bone Medical.

“We now know that earlier work showing a reduction in TNF release in animal cells is replicated in human cells, by preventing the expression of TNF. This finding is an important piece of the puzzle because a different mechanism of action could have lead to a different outcome. For example, suppressing the release of TNF could produce unknown adverse effects due to a build up of TNF in these cells. Understanding the outcome of this study is of particular importance for the project as a whole.”

Professor Peter Brooks, Executive Dean of Health Sciences at the University of Queensland and Immediate Past Chairman and Committee Member of the “Bone & Joint Decade” National Action Network said, “Rheumatoid arthritis continues to cause very significant pain and disability around the world. Although treatments such as TNF alpha inhibitors have made a big difference in many patients in terms of reduction of pain, these treatments require injections at regular intervals. There is a real need to develop an oral therapy that really does suppress the disease and enable patients with RA to continue to lead as normal lives as possible.”

This view is supported by Professor Philip Sambrook, Head of Rheumatology at Sydney’s Royal North Shore Hospital and Director of the Institute for Bone & Joint Research, where the studies were completed. “Rheumatoid arthritis is a chronic disabling condition and new treatments are aimed at the underlying inflammatory process are needed. TNF has been identified as one of the key processes in inflammation in RA but current anti-TNF therapies have to be given by injection and are associated with side effects in some patients. An oral anti-TNF therapy would offer distinct advantages, especially if able to reduce TNF actions without completely ablating its actions”, he said.

“The next step for the project is to complete studies in an animal model of rheumatoid arthritis at the Institute for Bone & Joint Research in Sydney. Based on positive outcomes, we would move the project into human clinical testing late in 2006. Our aim is to make two significant improvements to treatments involving the regulation of TNF. One is the development of an oral

formulation to replace the current injectable treatments. The second is to achieve better control of TNF levels in the hope that we can reduce the symptoms of rheumatoid arthritis without losing any beneficial effects of TNF," Mr Redman said.

About rheumatoid arthritis

Rheumatoid arthritis (RA) is a chronic immune disorder affecting up to 15% of the American population, according to the Centers for Disease Control and Prevention (CDC). RA is significantly more prevalent in women than men, with 75% of the cases diagnosed in women. While RA can affect children and adolescents, the disease usually strikes adults between the ages of thirty and forty, and the incidence of clinical illness is greatest among those aged forty to sixty years.

There are numerous forms of arthritis, a term which refers to inflammation of the joints. RA affects about 1 percent of the population and is more common in women. RA involves attack by the body's immune system on the tissue that lines the joints. The symptoms of RA include pain and swelling of small joints, aching and stiffness in joints and muscles and loss of motion at the joint. Factors contributing to RA fall into the categories of genetic, hormonal, environmental and 'other'. The direct cost of arthritis in Australia in 2000 was estimated to be AUD2.2 billion. According to Med Ad News, the world market for arthritis drugs was USD14.5 billion and anti-TNF products exceeded USD4 billion in 2004.

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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*[™] oral calcitonin
- *Perthoxal*[™] oral parathyroid hormone
- bone cell regulators BN005/BN008

Arthritis

- TNF regulators BN006
- joint protection & collagen tolerance BN007