

INFORMATION RELEASE - 28 MAY 2008, BRISBANE

CBIO ANNOUNCES START OF PHASE II CLINICAL TRIAL IN RHEUMATOID ARTHRITIS

- First Phase II subcutaneous efficacy clinical trial for CBio
- Follows from intravenous dosing clinical trial with results published in The Lancet

Brisbane biotechnology company CBio Limited has commenced recruitment for a Phase II trial in rheumatoid arthritis (RA) for its lead product, XToll[®]. The study is CBio's first subcutaneous dosing clinical trial in patients with RA, and follows from the intravenous dosing clinical trial completed in 2006.

In 2006 CBio successfully completed three Phase II intravenous dosing clinical trials of XToll[®]. Data generated from the intravenous dosing Phase IIa rheumatoid arthritis clinical trial was accepted for publication in international medical journal The Lancet in September 2006 ([Vanags et al, Lancet 2006; 368: 855-63](#)). Findings through peer-review were that XToll[®] showed evidence of clinical effect in rheumatoid arthritis patients with well-established disease, while being well tolerated.

A similar paper recognising the therapeutic benefits in another indication, psoriasis, has just been published by the Archives of Dermatology. ([Arch Dermatol, 2008; 144: 683-685](#))

Clinical Trial Details

The study is designed to evaluate the safety and efficacy of XToll[®] using a randomised, double-blind, placebo-controlled design in subjects with rheumatoid arthritis. The primary objective is to evaluate the safety and tolerability of subcutaneous injections of XToll[®]. Each subject will receive their designated dose of XToll[®] or placebo twice weekly over the 12 and 24 week treatment period and will be monitored closely throughout. The study will be conducted throughout Australia and New Zealand. The Principal Investigator for the study is Dr Peter Nash of the University of Queensland. Patient recruitment has begun and dosing of the first patient is expected shortly.

Dr Peter Nash, Principal Investigator said:

"Rheumatoid Arthritis is the most common form of chronic inflammatory arthritis affecting Australians. It is a chronic and disabling condition. The pain and discomfort associated with RA can significantly affect a person's quality of life – it reduces longevity and a significant number of patients become severely disabled and unable to work after 5 years. Up to 4 out of 10 patients do not respond effectively to existing treatments for RA. This new therapy has the potential to be a very important breakthrough for RA sufferers."

Further information about the clinical trial can be found via the [Australia New Zealand Clinical Trials Registry](#), ACTRN12608000208303.

About CBio Limited

CBio Limited is an Australian unlisted public biopharmaceutical company established in 2001 to develop technologies for the treatment of autoimmune and inflammatory diseases. CBio's lead product is XToll[®]. XToll[®], or recombinant chaperonin 10 (Cpn10), is a modified version of the naturally occurring protein chaperonin 10.

In 2004, CBio in partnership with the University of New South Wales and the University of Queensland was awarded two Australian Federal Government Linkage Grants to fund collaborative research. In 2005 CBio was granted \$6 million in funding under the Federal Government Pharmaceutical Partnerships Program (P3). In 2007, CBio welcomed to its Board of Directors: Dr Goran Ando, Vice Chairman Novo Nordisk; Dr Peter Corr, General Partner Celtic Therapeutics; and Professor John Funder, Professor of Medicine at Monash University.

CBio's Board is supported by scientific advisors with international reputations in the autoimmune field including: Professor Peter Brooks, Executive Dean of Health Sciences at the University of Queensland; Dr Andreas Suhrbier, Head of the Queensland Institute of Medical Research Immunovirology Laboratory; Dr Eicke Latz, Assistant Professor at the Department of Infectious Diseases and Immunology, University of Massachusetts; and Dr Pam McCombe, Senior Research Fellow - Neuroimmunology Research Unit, Department of Medicine, University of Queensland.

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