

T +61 7 3871 3455

F +61 7 3871 3477

E info@medica.com.au

www.cytopia.com.au

ACN 079 253 606



Cytopia Limited

PO Box 820

Level 12

Toowong Business Centre

Toowong Tower

Toowong QLD 4066

9 Sherwood Road

Australia

Toowong QLD 4066

Australia

## Media Release

20 July 2004

# XENOME'S PAIN DRUG XEN2174 ENTERS HUMAN CLINICAL TRIALS

Cytopia Limited (ASX:CYT) is pleased to announce that Xenome has commenced a Phase I clinical trial on its severe pain drug candidate Xen2174. The results of the trial are expected during the last quarter of this calendar year.

Dr Kevin Healey, Cytopia's Managing Director said, "the trial should provide information on the safety of Xen2174 and is an important milestone on the way to efficacy testing in humans".

Cytopia Limited, which recently changed its name from Medica Holdings, owns 22.4% of Xenome.

Xenome's Press Release is attached.

## ABOUT CYTOPIA LIMITED

Cytopia Limited (formerly Medica Holdings) is an Australian biotechnology company focused on the discovery and development of new drugs to treat cancer, immune disorders and cardiovascular diseases.

Cytopia Limited is a registered Pooled Development Fund and conducts its research and development *via* a subsidiary company Cytopia Research Pty Ltd.

## Cytopia Research Pty Ltd

Cytopia Research specialises in discovering new molecules that can inhibit enzymes known as kinases, an exciting new class of drugs.

It holds a worldwide exclusive license from the Ludwig Institute for Cancer Research to a number of these enzymes known as JAK1 and JAK2 kinases which are over-active in many inflammatory diseases and some cancers. These JAK kinases, which were discovered by

Cytopia's Chief Scientific Officer Dr Andrew Wilks, are well-validated drug targets and Cytopia has developed a number of inhibitors with therapeutic potential.

Cytopia applies structure based rational drug design techniques that can accelerate the identification of active molecules and their refinement into drug candidates.

### ***Cancer program***

Cytopia's candidate drug has shown efficacy in six *in vivo* animal models of various cancers, including prostate cancer, breast cancer, lymphoma and leukaemia.

Cytopia's candidate has entered formal preclinical testing during which short and long term toxicity will be assessed and clinical grade material will be manufactured. We currently expect the Phase I human trial to be in early 2005 subject to approval by regulatory authorities.

### ***Anti-Inflammatory Program***

Cytopia has generated highly specific and potent inhibitors of the JAK3 kinase which is of major interest to pharma companies for the prevention of transplant rejection and treatment of several inflammatory diseases such as asthma, dermatitis, psoriasis and eczema.

A number of pharma companies are either currently evaluating Cytopia's molecules or have expressed an interest to do so.

### ***Cardiovascular Program***

Cytopia has entered into a collaborative R&D Agreement with New York-based Myomatrix to explore the use of JAK2 inhibitors to treat a number of cardiovascular problems such as heart failure and pulmonary hypertension. Myomatrix has shown that JAK 2 inhibitors are effective in an *in vivo* model of heart failure.

Cytopia and Myomatrix plan to test one or more of Cytopia's molecules in animal models of pulmonary hypertension and heart failure in calendar 2004.

## **Cytopia's other Assets**

**Xenome Limited** last month gained Investigatory New Drug approval by the US Federal Drug Administration for its novel anti-pain molecule, Xen2174 and a Phase I human trial commenced in July . (Cytopia owns 22.4%of Xenome).

**Alchemia Limited** is ahead of schedule in its development of a generic version of synthetic heparin in partnership with Dow Chemical for manufacturing, and with American Pharmaceutical Products for marketing and regulatory matters. Alchemia has negotiated a 50:50 profit share with both companies.

In addition, Alchemia has made good progress in applying its VAST™ technology platform to the discovery of drug leads for cancer and novel antibiotics. (Cytopia owns 14.3% of Alchemia).

For more information please contact either:

Dr Kevin Healey  
Chief Executive Officer

Tel: +0409 413 402

Email: [kevin.healey@cytopia.com.au](mailto:kevin.healey@cytopia.com.au)

Dr Andrew Wilks  
Chief Scientific Officer

Tel: +61 3 9522 6911

Email: [andrew.wilks@cytopia.com.au](mailto:andrew.wilks@cytopia.com.au)

Mr Nicholas Mathiou

Finance Director

Tel: 07 3871 3455

[nicholas.mathiou@cytopia.com.au](mailto:nicholas.mathiou@cytopia.com.au)

Or, visit our website at: [www.cytopia.com.au](http://www.cytopia.com.au).



*Biopharmaceutical  
Discovery*

**MEDIA ANNOUNCEMENT**

XENOME'S PAIN DRUG XEN2174 ENTERS HUMAN CLINICAL TRIALS

**Tuesday, 20 July 2004 Queensland Australia:** Biotechnology company, Xenome Limited, announced today that a Phase I clinical trial had commenced on its promising neuropathic pain drug Xen2174.

The Phase I trial is a randomised, placebo-controlled, double blind, dose-escalating study involving up to 20 healthy male volunteers. The primary purpose of this trial is to evaluate the safety and tolerability of Xen2174 following intravenous administration.

"Additional information on the pharmacokinetics and potential anti-nociceptive effects of Xen2174 will also be examined during the trial", commented Xenome's Head of Drug Development, Dr Michael Thurn.

In previous animal studies Xen2174 was shown to relieve the pain associated with nerve damage. This form of neuropathic pain is commonly found in patients with shingles, diabetic neuropathy, chronic back pain, HIV/AIDS and cancer.

Following the successful completion of the Phase I trial, further clinical testing of Xen2174 is planned in cancer patients with intractable pain later this year.

Xenome's CEO and Company Director, Dr Tony Evans said, "the trial initiation represents one of several value adding milestones recently completed by the company, including the filing of an IND with the US Food and Drug Administration (FDA) and the further investment of \$2 million from QBF bringing its total investment in Xenome to \$6 million."

Xenome has contracted CMAX, a division of the Institute of Drug Technology Australia Ltd., in Adelaide to conduct the Phase I clinical trial. Results of the trial are expected to be available during last quarter of 2004.

**About Xen2174**

Xen2174 represents a new class of molecules, called the chi conopeptides derived from the venom of the coneshell, a marine shellfish that is abundant on the Queensland Great Barrier Reef. Xen2174 has been shown to selectively inhibit the Norepinephrine Transporter (NET) a known drug target in the central nervous system. In the spinal cord Norepinephrine (NE) is the dominant neurotransmitter activating the descending inhibitory pain pathway. Delivery of Xen2174 directly into the space around the spinal cord deposits the drug adjacent to NET so that in episodes of pain, the inhibition of NET by Xen2174 elevates the levels of NE leading to

the activation of inhibitory pathways preventing pain signals from reaching the brain. In animal models of pain, Xen2174 has been shown to provide superior pain relief when compared to morphine. Xen2174 is currently under development for the treatment of severe cancer pain, a market estimated to be worth over US\$4 billion.

### **About Xenome**

Xenome is a world leader in the discovery of novel peptides from animal venoms. Based in Brisbane, Australia, Xenome has generated a unique expertise in peptide chemistry to enable the production of a library of molecules from venoms. This library is now in demand by biotechnology and pharmaceutical companies in the USA and Europe. Peptides with unique chemistry and pharmacology are being used in Xenome's drug development activities which are focused on pain management, urological disorders, airway disorders and diseases of the central nervous system. Current major shareholders of the company are the Queensland BioCapital Fund (QBF), Cytopia Limited, an ASX listed biotechnology company, BioTech Capital Limited, an ASX listed biotechnology investment fund and UniQuest Pty Ltd, the commercialisation company of the University of Queensland.

### **For further information please contact:**

Tony Evans, CEO  
Xenome Limited  
Tel: +617 3720 8055  
E-mail : [tony.evans@xenome.com](mailto:tony.evans@xenome.com)  
<http://www.xenome.com>

