

Cytopia gets green light to trial promising new anticancer drug

Up to 30 patients with advanced incurable solid-tumours are to be involved in clinical trials of Cytopia's new potent and innovative anticancer drug CYT997.

Cytopia Managing Director, Dr Kevin Healey, said the company had obtained the necessary ethics approval to begin clinical trials at the Royal Brisbane and Women's Hospital in association with the Queensland Institute of Medical Research and Q-Pharm Pty Ltd. The tests will be supervised by leading ovarian oncologist, Dr Paul Vasey, and medical oncologist, Dr Jason Lickliter.

"Cytopia realised that there is a major unmet clinical need for new cancer drugs that lack the side effects of current first-line cancer drugs," he said.

"CYT997 was discovered entirely in Cytopia's laboratories by screening chemical libraries against cancer cells. It was then optimised using computer design and medicinal chemistry techniques."

Dr Healey said the Phase I trial was the first in a series of trials that, if successful, could result in the marketing of a novel anticancer drug.

"The clinical trials will indicate if CYT997 can

kill tumour cancer cells, while at the same time restricting blood flow to the tumour to prevent it from growing. If successful, we would launch the drug internationally."

Dr Healey said the study closely followed a successful preclinical toxicology program for CYT997 that showed the drug lacked cardiotoxicity and neurotoxicity in animals - hallmark safety concerns for other drugs currently marketed and under development for the treatment of cancer.

"While the trial patients will receive CYT997 by intravenous infusion once every three weeks for up

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The cancer drug market is huge and so could potentially be very valuable for Cytopia

...Kevin Healey



A Message from the MD

Welcome to the first issue of CyTopics. This newsletter is our way of informing shareholders, the market and those interested in the biotechnology industry about Cytopia's latest achievements, developments within the company and advances in our cancer, anti-inflammatory and cardiovascular programs.

It has been a very busy start to the year for us with exciting news regarding clinical trials of our new cancer drug CYT997, acquisition of New York-based Myomatrix, and important changes to our Board,

which will help consolidate the company's position in the dynamic biotechnology industry.

This issue also closely follows our half-yearly report, which reflected a strong cash position of just over \$17 million at 31 December 2004, after completing a Rights Issue to raise \$13.2 million. More details about these results can be found on page two of CyTopics.

I hope you find this bulletin both informative and interesting. We welcome your feedback by emailing info@cytopia.com.au.

*Kevin Healey
Managing Director*



Kevin Healey
Managing Director



Rod Lyle
Non-Executive Director

Rod Lyle has been consistently rated as one of the leading Mergers and Acquisitions lawyers in Australia by 'The Asia Pacific Legal 500'. His professional qualifications and memberships include:

- *Master of Business Administration with Award of Distinction for Excellence, Melbourne Business School 2001*
- *Leadership in Professional Service Firms, Harvard University, Graduate School of Business Administration 1997*
- *Master of Laws, London University 1980*
- *Bachelor of Commerce, Melbourne University 1977*
- *Bachelor of Laws, Melbourne University 1977*
- *Member, Law Institute of Victoria; Law Society of New South Wales; Law Society of London*

Cytopia strengthens Board

One of Cytopia's key strengths is the calibre of its people – from scientists researching the latest in cancer, cardiovascular and anti-inflammatory drugs to Board members leading the company in the competitive biotechnology industry.

The latest person to join Cytopia's team is Rod Lyle as Non-Executive Director.

Cytopia Executive Chairman, Bob Watson, said Rod was one of Australia's leading commercial lawyers and had been a key adviser on a number of significant mergers and acquisitions during his 28-year career.

Mr Watson said he would like to thank two outgoing Directors, Don Hulme and Nicholas Mathiou, for their dedication and contribution to Cytopia over the last seven years. Mr Mathiou has remained as Chief

Cytopia's planned growth and development necessitates a broader skill set within the Board, particularly in relation to mergers and acquisitions

... Bob Watson

Financial Officer and Company Secretary.

"On behalf of the Board and shareholders, I would like to thank Don and Nicholas for their outstanding efforts and devotion to the company," he said.

Cytopia Managing Director, Kevin Healey, said the Board changes reflected the company's absolute focus on drug discovery and its desire to add international biotechnology industry experience as well as merger and acquisition skills.

Strong half-yearly results show way forward

Cytopia is actively pursuing growth opportunities, including merger and acquisition prospects, following its strong half-yearly results released earlier this year.

The company reported a favourable cash position of just over \$17 million at 31 December 2004, having completed a Rights Issue to raise \$13.2 million, and the sale of its interest in Xenome Limited for \$3.75 million.

Cytopia renewed its commitment to a cardiovascular drug research program with the acquisition of the assets and operations of New York-based Myomatrix. The appointment of Executive Chairman, Bob Watson, also strengthened the commercial strategy of the company.

Mr Watson said the first half result demonstrated the company was delivering on its revised strategy and had put itself in a good financial position to progress key programs in cancer, immune disease and cardiovascular drug discovery.

"The company has never been stronger in both its cash position and the development of its pipeline of drug candidates," Mr Watson said.

Cytopia Managing Director, Kevin Healey, said the company had sufficient funds to not only take its cancer drug candidate CYT997 through several Phase 1 trials, but also accelerate several drug leads for other indications into the preclinical testing stage over the next one to two years.

"All of the company's financial results are in line with or better than expectations," he said.



Bob Watson has more than 20 years executive management experience in the information technology and recruitment industries. He has been Chief Executive Officer of Mayne Nickless Computer Services, the United Kingdom's Data Sciences International and Lend Lease Employer Systems. Bob was also Australasian CEO for Adecco - the world's largest recruitment and labour contracting agency. He is currently a Director of several companies including SEEK.

Cytopia Inc to expand heart drug research

Cytopia Inc will expand the cardiovascular research program of New York-based Myomatrix following the recent acquisition of the US company's assets by Cytopia Research Pty Ltd.

Cytopia Executive Chairman, Bob Watson, said Cytopia Inc was established as a wholly-owned subsidiary of Cytopia Research, which will hold all future intellectual property.

"The key asset of Myomatrix is a world-wide exclusive licence from the State University of New York covering the application of JAK2 kinase inhibitors for the treatment of cardiovascular diseases such as heart failure and pulmonary hypertension," he said.

"This transaction also establishes Cytopia in the US market and delivers the first step in our strategy to grow our business in larger markets in a very synergistic way.

"The operation of Cytopia Inc will significantly expand our technology into another major therapeutic area," Mr Watson added.



Cytopia Managing Director, Kevin Healey, said the acquisition had been a logical extension of a research collaboration that Cytopia had with Myomatrix over the past year.

"Cytopia and Myomatrix have shown that highly specific and potent kinase inhibitors developed by Cytopia can block signalling pathways in cardiac myocytes that are associated with heart failure," he said.

"We are currently testing our lead molecules in animal models of pulmonary hypertension and heart failure with results expected by the middle of this year."

Cytopia Inc is based in Albany, New York and has retained existing Myomatrix Executives Dr Larry Zisman and Dr Shreefal Mehta.

Cytopia files IND

Cytopia has filed an Investigational New Drug Application (IND) with the Food and Drug Administration (FDA) in the United States to seek approval for CYT997 clinical testing in the US.

Cytopia Managing Director Kevin Healey said the IND filing was a major milestone as it represents the culmination of a rigorous and successful drug development program aimed at providing efficacy and safety in animals to support a human clinical investigation of CYT997.

"The IND provides the necessary information required by the FDA to decide whether clinical studies can be conducted in the US with CYT997, including its safety profile in animals and the proposed clinical trial protocol," he said.

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to six cycles, the drug may also be orally available," he said.

"CYT997 appears to avoid some of the mechanisms that enables tumours to become resistant to existing first line drugs. The primary goals of this study are to evaluate the safety and tolerability of CYT997, to assess its behaviour in vivo and to establish a safe dose of CYT997 for subsequent Phase II clinical trials."

"This trial, which should be completed in about nine months, is also designed to identify any preliminary signs of anticancer activity."

Dr Healey said the drug had proven to be effective in animal models of various cancers including prostate, colon and breast cancer, lymphoma and leukaemia.

"We have completed a rigorous preclinical evaluation of the safety and toxicology of the drug in several animal species that cleared the way for

human trials," he said.

The thorough process of testing new drugs, including safety reviews, clinical trials and the international marketing approval process mean that it could be between five and eight years before CYT997 is commercially available.

"We are very excited about a number of features of the drug - its dual mode of action, potential for less resistance to emerge and, particularly the expectation that it will be orally active, a very novel feature amongst anticancer drugs," Dr Healey added.

Cancer is still the leading cause of death in Australia with more than 36,000 people dying each year. More than 88,000 new cases of cancer are also diagnosed in Australia each year, while one in three men and one in four women will be directly affected by cancer before the age of 75.



We welcome your feedback

Your thoughts on CyTopics or the biotechnology industry are important to us and we would like to hear from you by sending your email address to info@cytopia.com.au.

You can also access CyTopics at www.cytopia.com.au.

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At-A-Glance

As an Australian drug discovery and development company, Cytopia is committed to redefining the way medicines are discovered. It is positioned at the cutting-edge of structure-based rational drug design and discovery, with a vision to develop a new generation of therapeutic drugs for cancer and immune disease.

Already, Cytopia has applied its medicinal chemistry capability, high-throughput screening facility and computational chemistry platform to develop a broad pipeline of novel pre-clinical drug candidates. Its fully integrated laboratory facility is located in the heart of Melbourne and has links to the Baker Heart Research Institute, the Alfred Hospital and Monash University.

Cytopia is focusing its drug development on major areas of clinical need including cancer (prostate, colon, breast, lymphoma, leukemia, and multiple myeloma), immune disease (including rheumatoid arthritis, eczema and asthma) and cardiovascular disorders.

The company has built up an impressive portfolio of granted patents and patent applications protecting significant intellectual property, including both proprietary drug discovery targets and new Composition Of Matter patents on novel drug-like enzyme inhibitors.

Cytopia's share in Alchemia Limited

Cytopia owns 14.4 million shares in Alchemia Limited, which has made good progress in applying its VAST™ technology platform to the discovery of drug leads for cancer and novel antibiotics.

Alchemia is also on schedule in its development of a generic version of synthetic heparin. Alchemia is in partnership with Dow Chemical for manufacturing heparin and with American Pharmaceutical Products for marketing and regulatory matters.



Cytopia Research

Cytopia Research Pty Ltd holds a worldwide exclusive licence from the Ludwig Institute for Cancer Research to a number of enzymes known as JAK1 and JAK2, 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.

Cytopia presents cancer data in US

Cytopia's Dr Ian Phillips presented a poster at the American Association of Cancer Research meeting in Anaheim, California during April. The poster describes the novel dual mode of action of Cytopia's cancer drug candidate CYT997 (see page 1). The poster also explains how CYT997 closes down the blood vessels supplying a tumour and the mechanism by which it kills cancer cells.