

MEDIA RELEASE

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CYTOPIA GETS GREEN LIGHT TO TRIAL PROMISING NEW CANCER DRUG

Up to 30 patients with advanced incurable solid-tumours are to be involved in clinical trials of a potent new anticancer drug (CYT997), developed by Australian biotechnology company, Cytopia Limited.

Cytopia Managing Director, Dr Kevin Healey, said the company had obtained the necessary ethics approvals 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.

"In animal studies, CYT997 was highly effective in killing cancer cells including prostate, colon and breast cancer, lymphoma and leukaemia. Based on this success, we are confident to proceed to human clinical trials," Dr Healey said.

"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.

"We are very excited about a number of features of the drug. It has a dual mode of action, directly killing cancer cells and at the same time starving the cancer of its blood supply.

"Cancers rely on this blood supply for their growth," he said.

Dr Healey said the drug looked like it would be effective when taken orally which would be a major benefit for patients.

"In addition, CYT997 appears to avoid some of the mechanisms that enable tumours to become resistant to existing first line drugs," he said.

Cytopia's Chief Scientific Officer, Dr Andrew Wilks said that the Phase I study would be a non-blinded, dose escalation study in patients with various cancers and could take between nine and twelve months.

"Patients will receive CYT997 by intravenous infusion once every three weeks for up to six cycles," Dr Wilks said.

“The primary goals of this study are to evaluate the safety and tolerability of CYT997, to assess its behavior in vivo and to establish a safe dose of CYT997 for subsequent Phase II clinical trials.

“In addition, we will be looking for signs that the drug is having an effect on the cancers, particularly at the higher doses,” he said.

According to the American Cancer Society, there will be about 1.3 million new cases of cancer in the US in 2005, not including skin cancers. Approximately 570,000 deaths are expected in 2005 in the US alone. The National Institutes of Health estimate direct medical costs for cancer in 2004 at \$69.4 billion.

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.

Cytopia Limited is focused on the discovery and development of new drugs to treat cancer, immune disorders and cardiovascular diseases. The company is a registered Pooled Development Fund and conducts its research and development via a subsidiary company, Cytopia Research Pty Ltd.

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ABOUT CYTOPIA LIMITED

Cytopia Limited 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 (CYT997) has shown efficacy in *in vivo* animal models of various cancers, including prostate cancer, breast, lymphoma and leukaemia.

A Phase I human trial will be commenced in May 2005 and will run for nine to twelve months.

Anti-Inflammatory Program

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

Cardiovascular Program

Cytopia recently bought the assets of Myomatrix Therapeutics LLC, based in Albany New York and established Cytopia Inc as a wholly-owned subsidiary to continue and expand the cardiovascular drug research being conducted by Myomatrix. The priority areas are heart failure and pulmonary hypertension.

Cytopia owns 14.4 million shares in Alchemia Limited

Alchemia (ASX Code: ACL) is on 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.