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Media Release

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Cytopia anticancer drug accepted into Cancer Research UK's Clinical Trial Program

22nd November, 2004, Melbourne. In a boost to its anti-cancer drug program, Melbourne biotech Cytopia Ltd announced at its AGM today that its novel anticancer drug, CYT997, has been accepted by Cancer Research UK into its clinical trial program, allowing Cytopia direct access to leading British oncologists and world-class clinical trial facilities.

Cancer Research UK is a non-profit cancer research organisation specialising in the rapid advancement of promising anticancer agents. Cancer Research UK has taken over 100 new drugs into man for the first time.

CYT997 is a novel microtubule-targeting agent specifically developed by Cytopia research scientists to be orally active. In animal models of cancer orally administered CYT997 significantly inhibited tumour growth without adverse effects.

Cytopia's Chief Scientist Officer, Dr Andrew Wilks, explained that the experimental data on the anticancer properties of CYT997 was reviewed by Cancer Research UK's New Agents Committee (NAC).

"The NAC assessed CYT997 for originality, potential therapeutic benefit and likelihood of clinical success", Dr Wilks said. "The NAC's recommendation to accept CYT997 for clinical development independently verifies the enormous clinical potential of CYT997", he added.

Cytopia's Chief Executive Officer, Dr Kevin Healey, indicated that the acceptance by Cancer Research UK was an enormous boost to Cytopia's anticancer program allowing Cytopia direct access to leading British oncologists and world-class clinical trial facilities.

"Once contractual obligations are completed Cytopia expects the CYT997 phase 1 clinical trial to commence in early in 2005," he said.

Under a Clinical Trial Agreement Cancer Research UK would provide assistance to Cytopia in competing preclinical development of CYT997 and subsequently conducted the phase I clinical trial.

About CYT997

CYT997 is a potent wholly-synthetic small molecule that has potent anticancer properties. Technically, it is cytotoxic, disrupting microtubule formation by interacting with tubulin. In laboratory studies, low nanomolar concentrations of CYT997 inhibited the growth of a broad range of different human haematological and solid tumour cancer cell lines. Cancer cells known to be expressing MDR phenotype were not resistant to the potent cell inhibitory effects of CYT997. In subcutaneous and orthotopic animal efficacy studies, orally administered CYT997 significantly inhibited primary tumour growth of experimentally grafted human and mice cancer cells without adverse effects.

About Cancer Research UK

Cancer Research UK is the largest volunteer-supported cancer research organisation in the world, supporting the work of over 3,000 scientists. Cancer Research UK's annual scientific spend is over £213 million. Cancer Research UK's vision is to conquer cancer through world-class research, aiming to control the disease within two generations. Cancer Research UK's portfolio targets all aspects of cancer in 4 broad areas – the biology and causes of cancer, developing cancer treatments, cancer prevention and improving quality of life.

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 has shown efficacy in six *in vivo* animal models of various cancers, including prostate cancer, breast, 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).

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