

## **MEDIA RELEASE**

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# **Cytopia commences Phase II cancer drug study**

*Cytopia's first Phase II clinical trial*

Cytopia Limited (ASX: CYT) has obtained regulatory approval to proceed with a Phase II clinical study assessing its lead anti-cancer drug in up to 24 multiple myeloma patients. Patient enrolment will soon commence.

This Phase II study is the first in a number of further clinical studies planned for the anti-cancer vascular-disrupting agent CYT997 and will be conducted at the Alfred Hospital in Melbourne. It will investigate the activity of CYT997 in patients with relapsed or refractory multiple myeloma.

Multiple myeloma is an incurable cancer of plasma cells of the bone marrow, where the cells divide in an uncontrolled manner invading not only the marrow but the solid bone tissue. The human clinical trial follows promising laboratory studies which indicate that CYT997 potently disrupts myeloma cells, including those collected from patients with the disease.

While some significant advances in myeloma therapy have occurred in recent years, disease recurrence almost always occurs with increasing drug resistance leading to uncontrollable and fatal disease.

To be eligible for the study, patients must have failed at least one previous line of approved therapy. The trial is a single-arm, two-stage design with an interim analysis after 14 patients and maximum enrolment of 24 subjects. The company anticipates releasing interim data for this study in the third quarter of 2008.

"We are keen to unlock the potential of CYT997 as a next-generation cancer drug, particularly in indications with unmet medical need," said Mr Andrew Macdonald, CEO of Cytopia. "This study is the first of Cytopia's planned suite of Phase II studies for CYT997 and is a substantial value-adding milestone for the company."

The market for multiple myeloma drugs was estimated at US\$930 million in 2006 and is expected to grow to approximately US\$3 billion by 2013.

Cytopia is also currently conducting a Phase I study investigating the safety and tolerability of CYT997 following oral administration. The company also intends to file regulatory applications in support of other Phase II studies over the coming months.

The following table provides a summary of the key aspects of the Phase II multiple myeloma trial.

Name of trial	A prospective, single-arm, two-stage, open-label Phase II trial of CYT997 in relapsed and refractory multiple myeloma (CCL07001)
Primary endpoints	Determination of the overall response rate to CYT997
Secondary endpoints	Time to progression; number of cycles of CYT997 to achieve maximum response; overall survival and safety and tolerability
Blinding status	Not blinded
Product development status	Drug substance and drug product are manufactured to GMP standards
Treatment method	
Route	24 hour intravenous infusion dose
Frequency	Days 1 and 8 of a 21 day cycle
Dose-levels	202 mg/m <sup>2</sup> CYT997 dihydrochloride
Number of trial subjects	24 patients maximum.
Subject selection criteria	Eligible patients must have a diagnosis of multiple myeloma (per World Health Organisation criteria) and have received at least one but no more than three previous lines of therapy
Trial location	Melbourne, Australia
Expected completion	Interim analysis (14 patients) Q3, 2008
Trial standard	ICH-GCP

Enquiries:

Mr Andrew Macdonald  
Chief Executive Officer  
T: +61 3 9208 4232

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

Dr Gregg Smith  
Director: Drug Development & Operations  
T: +61 3 9208 4234

[gregg.smith@cytopia.com.au](mailto:gregg.smith@cytopia.com.au)

## About Cytopia

Cytopia Ltd is an Australian biotechnology company focused on the discovery and development of new drugs to treat cancer. Cytopia conducts its research and development via subsidiaries based in Melbourne and New York and specialises in discovering new molecules that can inhibit enzymes known as kinases, an exciting new class of drugs.

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