

T +61 3 9522 6900

F +61 3 9510 9292

E cytopia@cytopia.com.au

www.cytopia.com.au

ACN 079 253 606



Cytopia Limited

PO Box 6492

Level 5

St Kilda Road Central

Baker Heart Research

Melbourne Victoria 8008

Institute Building

Australia

Commercial Road

Melbourne Victoria 3004

Australia

MEDIA RELEASE

9 August 2007

Cytopia Phase I intravenous trial for anti-cancer drug achieves primary objectives

Cytopia Limited (ASX: CYT) announced today that it has successfully concluded dose-escalation in its Phase I intravenous trial for CYT997, the company's anticancer vascular-disrupting agent and is pleased to provide preliminary data on this study.

The primary objectives of this safety and tolerability study have been met. These were to determine the maximum tolerated dose (MTD) and the dose-limiting toxicities (DLTs) for the compound when administered as a 24-hour intravenous infusion to patients with a diverse range of solid tumours on a three-weekly cycle.

"The conclusion of dose-escalation in this study is an important milestone in the development of CYT997", said Mr Andrew Macdonald, Chief Executive Officer, "Planning for the compound's future clinical program has been underway for sometime. We anticipate advancing the drug into Phase II clinical studies later this year".

"Given the broad clinical potential for vascular-disrupting agents such as CYT997, we intend to investigate the activity of the compound in a range of cancer indications. Planning for both single-arm and randomised Phase II studies in combination with standard chemotherapies is currently being finalised."

The company is also conducting a second Phase I dose-escalation study of CYT997 as an oral capsule formulation. This oral trial, which is partly funded under a \$3.0m Commercial Ready grant, is being conducted at two locations in Queensland, Australia and is expected to conclude by December 2007.

Preliminary trial data

CYT997 was comparatively well tolerated in this study with the maximum tolerated dose in cancer patients (358 mg/m²) at least five-fold greater than doses tolerated in preclinical toxicology studies.

Two reversible dose-limiting toxicities were observed, namely a prolongation of the QTc interval (CTCAE Grade 3) and hypoxia/dyspnoea (shortness of breath; Grade 4). These toxicities were transient and were similar to those observed in Phase I studies for other vascular-disrupting agents.

Patients entering the trial had advanced cancer which had failed to respond to other therapies or for which no other therapy exists. Each was eligible to receive a maximum of six cycles of CYT997 therapy, subject to clinical status. A number of patients still remain on study and continue to receive the drug. Ongoing access to the drug under the Commonwealth Government's Special Access Scheme (SAS) has been available to those patients who have completed the maximum number of dosing cycles.

Secondary objectives of the Phase I study included the determination of a recommended dose for Phase II studies; pharmacokinetic assessment and a preliminary investigation of the anti-tumour properties of the compound. Analysis of biological and clinical data from the study is currently ongoing and the company expects to present a finalised trial report, including a complete list of adverse events and the recommended dose for Phase II studies, within two months.

The following table provides a summary of the key aspects of this trial.

Name of trial	A Phase I dose-escalation study of CYT997 given as a 24-hour intravenous infusion every three weeks in patients with solid tumours (QP04C07).
Primary endpoints	Determination of the dose-limiting toxicities and maximum tolerated dose of CYT997 given as a 24-hour intravenous infusion.
Secondary endpoints	Pharmacokinetics; definition of recommended dose for Phase II studies; preliminary evaluation of vascular-targeting activity.
Blinding status	Not blinded.
Product development status	Drug substance and drug product are manufactured to GMP standards.
Treatment method	
Route	Intravenous infusion
Frequency	Three weekly cycle.
Dose-levels	Dose-escalation study over 12 dose-levels (7 to 358 mg/m ²)
Number of trial subjects	31
Subject selection criteria	Eligible patients must have a solid tumour that is metastatic or unresectable for which standard therapies do not exist or are no longer effective.
Trial location	Brisbane, Australia.
Trial standard	ICH-GCP

About Cytopia

Cytopia Ltd is an Australian biotechnology company focused on the discovery and development of new drugs to treat cancer and other diseases. 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.

For more information please contact:

Mr Andrew Macdonald
 Chief Executive Officer
 T: +61 3 9522 6920
 E: andrew.macdonald@cytopia.com.au

Dr Gregg Smith
 Director, Drug Development
 T: +61 3 9522 6933
 E: gregg.smith@cytopia.com.au

or, visit our website at: www.cytopia.com.au