

ASX ANNOUNCEMENT

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Anti-cancer drug CYT997 update

Cytopia Limited (ASX:CYT) has commenced dosing patients in the first of a suite of Phase II clinical studies for its vascular disrupting agent (VDA), CYT997. These studies will investigate the activity of this anti-cancer compound in specific cancer types with high unmet medical need and poor prognoses.

VDAs are a new class of drugs to treat cancer and have potential for “blockbuster” sales in the treatment of vascularised tumours. CYT997 has a dual mechanism of action shutting down established blood vessels that supply the tumour with nutrients and oxygen and also direct cytotoxic properties. Capable of being delivered orally as well as intravenously, the compound was discovered by Cytopia scientists in 2003 and an Investigational New Drug application was accepted by the US Food and Drug Administration in 2005 to commence Phase I studies.

During the 2008 financial year Cytopia has:

- commenced dosing in its first Phase II study
- finalised preparations for its second Phase II study
- concluded its first Phase I safety and tolerability study with intravenous administration
- continued dose-escalation in its Phase I capsule dosing study (oral administration)

Phase II clinical programs

1. Phase II trial in multiple myeloma

Cytopia commenced dosing in its first Phase II efficacy study in patients with relapsed or refractory multiple myeloma in January 2008, some four months after conclusion of its initial Phase I study. The Phase II study is a two-stage design with an interim clinical activity analysis after 14 patients and maximum enrolment of 24 patients. Enrolment into this efficacy study is progressing to schedule and Cytopia anticipates undertaking interim data analysis by September this year.

This clinical study follows an extensive body of preclinical studies, including studies in cells from heavily pre-treated patients where CYT997 demonstrated significant anti-myeloma activity. The potential activity of this compound in multiple myeloma extends the utility of the drug beyond the core focus of the Phase II studies in conventional solid tumours.

Cytopia also intends to file an Orphan Drug Designation application in the United States for CYT997 in multiple myeloma within three months. Orphan drug designation gives a range of development benefits including extended patent protection and increased regulatory consultation.

2. Phase Ib/II trial in glioblastoma multiforme (GBM)

Cytopia is on schedule to commence a Phase II study for CYT997 in GBM during the second quarter of 2008. CYT997 will be administered in combination with two other approved anti-cancer agents.

GBM is an aggressive brain tumour commonly treated with radiotherapy, surgical resection and chemotherapy. Unfortunately, many patients relapse and subsequently have very poor prognoses. Experimental therapies which attack GBM blood vessels have shown promise in treating this condition and Cytopia intends to investigate the activity of its own vascular targeting agent CYT997 in this setting.

This clinical study will initially investigate the optimal safe dose for CYT997 when administered with the standard chemotherapy (Phase Ib). Following this initial safety assessment, the Phase II efficacy study will commence in a two-stage design with scheduled interim analysis. It is anticipated that 25 to 30 patients will be enrolled into this study at sites in Australia, the United States and the United Kingdom over an 18 month period. Overseas site selection will be finalised within three months.

The study will also use advanced imaging techniques such as specialised MRI to detect changes in tumour blood vessels as a marker for CYT997 activity. Interim data should be available by June 2009 with final data for this program in late 2009.

3. Further Phase II clinical trials

Following favourable findings in mesothelioma patients in Cytopia's Phase I trial, the company is undertaking feasibility analysis for a Phase II study in mesothelioma patients who have failed the currently approved drug, Alimta (pemetrexed). This single-arm study of 20-30 patients would potentially be conducted at multiple centres in Australia, the United States and Asia. Activity in second-line mesothelioma could lead to expedited drug approval and a fast-to-market strategy for the compound in this cancer indication.

It is anticipated that appropriate regulatory submissions to support this study will be filed in the third quarter of 2008.

In consultation with its clinical advisory board, Cytopia is continuing to refine its clinical development plan for further Phase II studies including randomised studies in conditions such as melanoma and for Phase III studies as new data arise from its preclinical and clinical activities.

Phase I clinical program

1. Phase I capsule clinical study

Cytopia has continued to accelerate dose-escalation in its Phase I oral capsule safety and tolerability study during the past 6 months.

Data collected from this study to date suggests that the compound is generally well tolerated following oral administration and that further increasing doses of CYT997 are warranted. Patient enrolment into this study will continue until the maximum tolerated dose for CYT997 after capsule administration is determined.

Dosing in this study to date has been conducted at sites in Brisbane and Townsville, although the Townsville site has been suspended due to the departure of the local principal investigator. Given the expanded patient enrolment, Cytopia is finalising ethical approval for the study at leading cancer centres in Adelaide and Melbourne and anticipates commencing dosing at these new sites in the next four weeks.

The addition of the two new trial centres will further accelerate dosing in this study. Initiation of these clinical centres also broadens the company's clinical partners and lays a foundation for the company's Phase II program. Given the generally favourable tolerability seen to date, it is not anticipated that the trial will conclude before the third quarter of 2008.

2. Phase I intravenous infusion study

As previously reported, this study was successfully concluded in September 2007. Key findings from this study have guided the design and implementation of the company's Phase II study program. Data from the Phase I study has been accepted for an oral presentation in June 2008 at the 44th American Society of Clinical Oncology General Meeting in Chicago.

Preclinical studies

Following the observation of synergy between CYT997 and 5-fluorouracil (a standard chemotherapeutic agent) in preclinical studies, the company will soon commence an expanded program of preclinical combination studies. These are designed to determine which currently approved cancer therapies best synergise with CYT997's vascular targeting properties. Data from these studies will assist the company in the selection and design of later stage clinical programs.

The company will also shortly commission synthesis of a third GMP-grade batch of CYT997 to support its expanded clinical programs. Further preclinical toxicology studies designed to broaden the available dosing regimes for clinical studies will also commence in the next three months.

Together, these studies signal the company's ongoing confidence in, and commitment to, the clinical development of CYT997.

The development timeline for CYT997 compares very favourably with the other vascular disrupting agents currently in late stage clinical studies. By December 2008, some five years after the discovery of this compound, the company intends to be finalising the first of its Phase II studies and will have two further Phase II studies well established. Successful completion of these programs in concert with additional preclinical data will add significant value to Cytopia's leading drug asset.

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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, Australia 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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