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Cytopia commences Phase I oral trial for CYT997

Cytopia Limited (ASX: CYT) announced today that dosing in its Phase I clinical trial for CYT997 by oral administration had commenced at the clinical site in Brisbane.

Regulatory approval for the trial was granted in November 2006 following extensive review of further safety and drug product manufacturing information, as well as information from Cytopia's ongoing intravenous clinical study.

The oral trial, which employs accelerated dose-escalation, is designed to investigate the safety and tolerability of CYT997 given by mouth to patients with a diverse range of solid tumours on a three-weekly cycle. Biomarker studies, including the use of sophisticated imaging techniques to measure the permeability (or leakiness) of the tumour blood vessels, will also be performed as a foundation for future Phase II programmes. Studies to investigate the oral absorption of CYT997 are also being undertaken.

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

| | |
|----------------------------|---|
| Name of trial | A Phase I accelerated dose-escalation trial of CYT997 given as an oral capsule every three weeks in patients with solid tumours (CCL06001). |
| Primary endpoints | Determination of the dose-limiting toxicities and maximum tolerated dose of CYT997 given orally. |
| 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 | Oral capsule dose. |
| Frequency | Three weekly cycle. |
| Dose-levels | Dose-escalation study. |
| Number of trial subjects | ca 12-15. |
| 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. |
| Expected completion | Q3, 2007 |
| 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, immune disorders and cardiovascular 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.

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