

MEDIA RELEASE

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Cytopia files for CYT997 Phase I Oral Trial

Cytopia Limited (ASX:CYT) announced today that it has filed a supplement to its Investigational New Drug Application (IND) with the United States Food and Drug Administration to begin an oral Phase I study for CYT997, the company's novel vascular-targeting agent against cancer. Applications to the Ethics Committees of the clinical trials site in Queensland have also been submitted.

This second Phase I clinical trial for CYT997 will assess the safety and tolerability of the compound when given by mouth as a capsule dose and builds upon the ongoing Phase I intravenous infusion clinical trial. Biological activity information will also be collected to allow an early indication of compound activity in cancer blood vessels.

The oral trial will utilise an accelerated regime for dose escalation thereby minimising overall trial duration and allowing more rapid increases in doses for subject patients. Participating subjects will have solid tumours for which no other effective therapy is available.

Subject to regulatory approval, it is anticipated that the oral trial will commence in November this year and take approximately nine months to complete.

"The oral absorption and activity of CYT997 in preclinical models is one of several key advantages for this compound," said Dr Andrew Wilks, Chief Scientific Officer of Cytopia. "The leading vascular-targeting compounds currently in clinical development can only be administered by intravenous injection thereby limiting their usefulness in different clinical settings."

"This regulatory filing is the culmination of a body of work, including compound manufacture, preclinical toxicology and drug formulation over the last year," said Mr Andrew Macdonald, CEO of Cytopia. "The proposed trial represents the next step in the company's development strategy for CYT997 in achieving a highly effective and simple to administer cancer therapy."

This oral safety trial is supported by a \$3m AusIndustry grant, whereby matching funds are provided for the trial, as well as initial efficacy studies of CYT997 as either a monotherapy or potentially for use in combination with other anticancer drugs.

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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