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**Sydney, Australia**

## **ASX: NOX**

### **Noxopharm Limited**

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Director

##### **Dr Graham Kelly**

Chief Executive Officer  
Managing Director

##### **Dr Ian Dixon**

Non-Executive  
Director

## **INITIAL CLINICAL STUDY ANNOUNCED AND APPROVED**

Noxopharm Limited (ASX: NOX) confirms that its inaugural clinical study of experimental anti-cancer product, NOX66, is on schedule to open in December 2016.

The Phase 1a/1b study is being conducted in Georgia and has been cleared by the 2 selected hospital sites to commence, allowing details of the study to be posted today on-line.

The main purpose of the study is to test the safety and clinical benefit of using NOX66 in conjunction with carboplatin therapy in patients with late-stage solid cancers. The rationale is that NOX66 will enable drug-resistant cancers to respond to carboplatin in a meaningful and well tolerated way. The patients will have exhausted all standard treatment options so that any further response to carboplatin normally would not be anticipated. The patients will be drawn from the following cancer types: breast, lung, ovary, prostate, head & neck. More importantly, Noxopharm is anticipating that a meaningful response will be achievable using a lower than normal dosage of carboplatin.

Dr Kelly, Noxopharm CEO, said, "This study is an entirely fresh and unique approach to the problem of how to improve the generally low response rates of different cancers to chemotherapy as well as how to make cancers respond again to chemotherapy once they stop responding."

"The aim is to boost the killing effect of chemotherapy on cancer cells without having any effect on healthy cells, and to do this with a dosage of a chemotherapy drug such as carboplatin that should not cause any side-effects."

Patients will receive NOX66 in conjunction with carboplatin, starting with 3 monthly treatments with a low dose of carboplatin (AUC=4), followed by 3 monthly treatments of a standard dose of carboplatin (AUC=6). Patients will be monitored each 3 months for tumour response.

The study has an adaptive design meaning that in the event of significant tumour responses after either the low or standard carboplatin dose, the study can be expanded immediately into a Phase 2a arm through the recruitment of a further 20 patients.

The study is being conducted in Georgia because of the anticipated speed of patient recruitment, backed up by a high standard of health care and FDA-audited clinical trial sites. The Company recently visited the sites and is confident in the ability of those sites to meet the Company's expectations.

Enrolment will commence once formal approval is received from the Georgian Ministry of Health.

#### **About Noxopharm**

Noxopharm is an Australian drug development company with offices in Melbourne and Sydney. The Company has a primary focus on the development of drugs to address the problem of drug-resistance in cancer cells, the major hurdle facing improved survival prospects for cancer patients. NOX66 is the first pipeline product, with later generation drug candidates under development in an R&D program.

#### **About The Clinical Trial Program**

Noxopharm is pursuing the development of NOX66 as an adjunct therapy for both chemotherapy and radiotherapy. The current study is the only study currently proposed for use with chemotherapy. A major clinical study program involving radiotherapy currently is being planned.

#### **About NOX66**

NOX66 is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to protect idronoxil from being inactivated in the human body by Phase 2 metabolism. Its purpose is to ensure that most idronoxil administered remains in an active form. Idronoxil works by cancelling pro-survival mechanisms in cancer cells that allow the cells to resist the killing effects of chemotherapies and radiotherapy.

Control systems responsible for the development of resistance mechanisms are regulated by the enzyme, sphingosine kinase, which is over-active in most cancer cells. Idronoxil inhibits this enzyme indirectly through blocking the movement of protons across the cell membrane. This effect is limited to cancer cells because the proton pump in cancer cells is controlled by the enzyme, ENOX2, which is restricted to cancer cells.

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#### **Forward Looking Statements**

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as "aim", "anticipate", "assume", "believe", "continue", "could", "estimate", "expect", "intend", "may", "plan", "predict", "project", "plan", "should", "target", "will" or "would" or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company's control that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement. No representation, warranty or assurance (express or implied) is given or made by Noxopharm that the forward-looking statements contained in this announcement are accurate and undue reliance should not be placed upon such statements.