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## ASX: NOX

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## NOX66 CONFIRMED NON-TOXIC. TRIAL CLEARED FOR FULL ENROLMENT

- **Scheduled checkpoint review of safety clears NOX66 monotherapy**
- **First group of patients complete Phase 1a arm**
- **Phase 1b combination treatment now underway**
- **Full recruitment anticipated by late-July 2017**

Sydney, 5 June 2017: Noxopharm announces that clinical study NOX-001 has been given the green light by its Data Safety Monitoring Committee to proceed to complete recruitment of the remaining patients based on the absence of toxicity of the Company's front-line anti-cancer drug, NOX66.

As the first formal clinical study of NOX66, the Company was obliged to include a built-in safety checkpoint involving a review of the first group of patients who completed a 3-week run-in of NOX66 therapy alone. Further enrolment was mandated to be delayed until that review was conducted. The review concluded that the drug did not cause any untoward side-effects, in line with the Company's expectation.

The review has shown that 14 continuous days of NOX66 therapy (400 mg idronoxil daily) was not associated with any adverse events, clearing the way for resumption of the remaining patients.

The NOX-001 study involves patients with late-stage cancers of the breast, lung, ovary, prostate or head & neck who have stopped responding to chemotherapy and who have no remaining standard treatment options.

The aim of the study is to see if NOX66 can overcome resistance of cancer cells to chemotherapy, providing a significant anti-cancer response to the chemotherapy drug, carboplatin. A further aim is to see if this response can be achieved with a well tolerated, lower-than-normal dose of chemotherapy.

The study has two arms: a 3-week Phase 1a safety run-in arm comprising NOX66 alone (monotherapy) followed by a Phase 1b safety and efficacy arm comprising NOX66 plus carboplatin.

All patients in this first safety group have progressed onto the Phase 1b arm where

they are receiving the same dose of NOX66 in combination with carboplatin. The carboplatin is being delivered at a low dose (AUC=4) for 3x (1-monthly) treatment cycles, followed by a standard dose (AUC=6) for a further 3x treatment cycles. Patients will be reviewed for clinical response (including scans) immediately following the 3rd and 6th treatment cycles.

The study is anticipated to be fully enrolled by end of July 2017. An interim analysis can be conducted when all patients in each of 2 NOX66 dosage cohorts (400 mg and 800 mg idronoxil) have completed 3 and then 6 cycles of combination therapy.

A major benefit of this result is that it means that all subsequent clinical trials in the NOX66 program now can commence without the need for a monotherapy safety arm.

#### **About NOX66**

NOX66 is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to preserve the anti-cancer activity of idronoxil in the body and to enhance its drug-like behaviour.

Idronoxil is a kinase inhibitor that works by inhibiting a range of enzymes including sphingosine kinase and PI3 kinase that regulate cell pro-survival mechanisms and which are over-expressed in cancer cells, as well as inhibiting external NADH oxidase Type 2 (ENOX 2) which is responsible for maintaining the transmembrane electron potential (TMEP) in the plasma membrane of cancer cells and whose expression is limited to cancer cells. Inhibition of these enzymes results in disruption of key downstream pro-survival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapy.

#### **About Noxopharm**

Noxopharm is an Australian drug development company with offices in Sydney, Melbourne and Hong Kong. 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. The Company also has initiated a pipeline of non-oncology drugs.

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#### **Forward Looking Statements**

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