



Date: 22 May 2018

Sydney, Australia

**ASX: NOX**

**Noxopharm Limited**

ABN 50 608 966 123

**Registered Office  
and**

**Operational Office:**

Suite 3, Level 4  
828 Pacific Highway  
Gordon NSW 2072  
Australia

**Board of Directors**

**Mr Peter Marks**

Chairman

Non-Executive

Director

**Dr Graham Kelly**

Chief Executive Officer

Managing Director

**Dr Ian Dixon**

Non-Executive

Director

ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

## **NOX TO PRESENT END-OF-STUDY CLINICAL DATA AT AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) ANNUAL MEETING**

- **CEP-1 Study: NOX66 in combination with carboplatin in late-stage cancer**
- **Objective: dual benefit of improved anti-cancer effect and lower incidence of chemotherapy-associated side-effects**
- **Final study visits completed: no serious adverse events related to use of NOX66**
- **ASCO presentation to focus on effect of treatment on progression of disease.**

**Sydney, 22 May 2018:** Noxopharm (ASX: NOX) today announces that

- the Company's first-in-human study of NOX66 has concluded with the last patient visit,
- an analysis of the safety data shows no serious adverse events associated with use of NOX66,
- an early review of disease status shows patients with stable disease or better after 6 months of therapy, and
- a poster containing data relating to patient safety and disease progression over the course of the study (data still under review) will be presented at the 2018 Annual Meeting of ASCO in Chicago on Monday 4 June, 8:00am CDT (Monday 4 June, 11:00pm AEST).

### **CEP-1 Study**

The Phase 1 CEP-1 Study is the opening study in the Company's Chemotherapy Enhancement Program (CEP). The objective of this program is to improve the outlook for patients receiving cytotoxic chemotherapy for the treatment of late-stage cancers. NOX66 is intended simultaneously to boost the anti-cancer effect of the chemotherapy by restoring sensitivity of cancer cells to the drugs, while at the same time seeking to reduce the incidence of side-effects. The Company believes that if this can be achieved, then NOX66 has the potential to become a standard of care addition to cytotoxic chemotherapy in late-stage cancer.

CEP-1 involves 19 patients with late-stage cancers (breast, ovarian, lung, prostate) that had stopped responding to standard treatment options. Study treatment was 6x 1-monthly rounds of chemotherapy involving a single injection of carboplatin combined with 14 days of NOX66; the first 3 rounds used a dose of carboplatin half of the standard dose, followed by 3 rounds of a dose three-quarters of the standard dose. Two different dosages of NOX66 were used (400 and 800 mg daily). Patients were assessed clinically for the incidence of side-effects and scanned at 0, 3 and 6 months for their disease status (RECIST response).

### **Data reporting**

NOX previously reported (6 March 2018) that 14 patients with evaluable disease completed the first 3 cycles (3 months) of treatment. In terms of safety, no serious adverse events were observed; in terms of disease status, 12/14 patients showed no disease progression (1 partial response; 11 stable disease) and were eligible to continue to receive the combination treatment, while 2/14 had disease progression.

The data to be reported at ASCO is an update taking in the full 6 cycles of treatment with a focus on two particular aspects: first, the disease status and side-effect profile of the 12 patients who underwent the final 3 cycles of treatment (total 6 months); and second, the overall progression of disease including the pre-study medical history.

### **Commentary**

Dr Graham Kelly, Noxopharm CEO, said, "We are continuing to analyse the data, and the ASCO poster on June 4 will be a comprehensive report on the progress of all patients in the study, including the incidence of side-effects (adverse events and serious adverse events) and disease status (incidences of partial responses, stable disease and disease progression). In the meantime, we have conducted sufficient analysis to be able to report here that the study has finished with no reports of serious adverse events being attributed to NOX66. Given that this is the first time that idronoxil has been administered to humans in a form we believe capable of preserving its potency, the lack of any serious side-effects is a key milestone for this drug candidate."

Kelly added, "CEP-1 is a sighting study, mainly designed to provide clear evidence of safety, but also early signals of efficacy, both of which are needed to justify a Phase 2 study. The Company believes that CEP-1 has provided that evidence. After ASCO, we will be sitting down with our medical advisors to determine the most appropriate strategy for the next phase of the CEP program, which looks like being a multi-national Phase 2 study. All with the ultimate objective of offering a better outcome for patients with late-stage cancers."

### **ASCO**

ASCO Presentation Details:

Abstract #: 2585 (Submitted Feb 14, 2018)  
Title: A phase 1 study of NOX66 in combination with carboplatin in patients with end stage solid tumours.  
Time: Monday June 4, 8:00-11:30 am (CDT)

.....

### **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 radiotherapies. Idronoxil also increases the activity of human NK cells.

### **About Noxopharm**

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney and Hong Kong. The Company has a primary focus on the development of drugs to sensitise cancer cells to radiotherapy and chemotherapy. NOX66 is the first pipeline product, with later generation drug candidates under development.

**Investor & Corporate Enquiries:**

Prue Kelly  
M: 0459 022 445  
E: [info@noxopharm.com](mailto:info@noxopharm.com)

**Company Secretary:**

David Franks  
T: +61 2 9299 9690  
E: [dfranks@fa.com.au](mailto:dfranks@fa.com.au)

[www.noxopharm.com](http://www.noxopharm.com)

**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.