Date 6 March 2018 **Sydney, Australia**

ASX: NOX

Noxopharm Limited

ABN 50 608 966 123

Registered Office:
and
Operations Office:
Suite 3, Level 4
828 Pacific Highway
Gordon NSW 2072
Australia

NOX REPORTS NOX66 CLINICAL DATA

- **NOX66 + low-dose carboplatin in late-stage cancers**
- **Disease progression blocked in the majority of patients (12/14) after 3 months**

6 March 2018, Paris: Noxopharm (ASX: NOX) today presented an update on its Phase 1b clinical study known as CEP-1 to the 2018 ESMO International Congress on Targeted Anticancer Therapies in Paris.

CEP-1 is being conducted at clinics in Georgia, including FDA-inspected sites. It involves patients with late-stage cancers of the lung, breast, ovary and prostate following disease progression after multiple courses of chemotherapy and who have no remaining standard treatment options. The study is fully recruited with the last patient due to complete treatment in April 2018.

This is the first study in the CEP (Chemotherapy Enhancement Program), a program designed to challenge the generally accepted notion that, to be effective, chemotherapy needs to be toxic. CEP aims to show that it is possible to achieve meaningful clinical benefit in patients with late-stage cancer using a chemotherapy drug regimen that is without significant side-effects. It further aims to show that this can be achieved in a high proportion of patients across a range of common cancer types such as breast and lung cancers.

The drug regimen being investigated initially is NOX66 in combination with low-dose carboplatin (AUC4 intravenously every 4 weeks), which on its own would not be expected to produce any notable anti-cancer effect in patients whose cancers have progressed in the face of previous chemotherapy.

Summary

The data from this study provides proof-of-concept evidence for the beneficial use and tolerability of NOX66 in combination with a low dose of carboplatin, and supports the Company's underlying belief that it is possible to deliver meaningful clinical benefit without compromising patient safety.

Fifteen (15) patients with evaluable disease underwent combination therapy.

Only 1 patient (1/15) experienced toxicity serious enough to warrant withdrawal from the study due to an allergic reaction to the carboplatin.

The remaining 14 patients were evaluated for disease status after 3 months of treatment:

- 1 showed a partial response
- 11 showed stable disease
- 2 showed disease progression.

The 12 cancers in patients who benefited were breast (5/5), ovarian (3/3), lung (2/4) and prostate (2/2). The partial response was an ovarian cancer.

Comment

Noxopharm CEO, Graham Kelly, said, "Any interpretation of this data comes with the usual caveat that this is a Phase 1b study and as such was not designed to give definitive efficacy data. But considering that the patients in this study had advanced disease which had failed standard therapies, being able to halt the disease process in such a high proportion of patients across 4 common cancers for at least 3 months is a notable outcome."

"To put this into perspective, a study using a recently approved immuno-oncology drug for late-stage lung cancer showed that just one in five patients responded to treatment and, on average, patients were alive for just 2.8 months longer than on standard therapy."

The main aim of the CEP project is to develop a well-tolerated treatment regimen that will provide meaningful clinical benefit in cancer patients unable to tolerate standard chemotherapy or who are not responding to new treatments such as the immuno-oncology drugs.

"The CEP-1 trial outcome leaves us sufficiently convinced that we are well on the way to achieving that goal, with a Phase 2 study currently being planned and due to start before the end of 2018. Our objective now is to see how long this clinical benefit will last once we continue treatment beyond 3 months", Kelly added.

Noxopharm has a major focus on developing NOX66 to enhance the anti-cancer effect of radiotherapy, both external beam radiotherapy and intravenous brachytherapy. The CEP program complements the radio-enhancement program (known as DARRT) by providing a choice of treatment as part of the move to personalise treatment according to individual cancer features and patient needs.

Study details

Patients started with a 2-week run-in of NOX66 alone to establish the tolerance of this drug. This was followed immediately by 3 months of combination therapy of NOX66 with low-dose carboplatin (AUC4 intravenously every 4 weeks), followed by 3 months of combination therapy with standard dose of carboplatin (AUC6 intravenously every 4 weeks) providing there was no evidence of disease progression. Patients were scanned prior to the study and then after each 3 months of combination therapy. Tumour

response was determined by RECIST criteria and designated as complete response, partial response, stable disease or progressive disease.

After allowing for voluntary withdrawals during the run-in arm, 15 patients underwent NOX66/low-dose carboplatin combination therapy (5 patients 400mg NOX66; 10 patients 800 mg NOX66).

The final patient scan is scheduled for mid-April 2018, with the final data including safety outcomes, RECIST outcomes and quality of life scores expected to be presented shortly thereafter.

……

About RECIST
Response Evaluation Criteria in Solid Tumors (RECIST) is an objective means of determining whether a cancer is improving ('responding'), staying the same ('stable disease') or worsening ('progressive disease'). Patients are scanned (usually CT or MRI) and all tumor lesions identified and counted, with up to 10 lesions ('target lesions') measured along their longest diameter (LD).
Complete response: disappearance of all target and non-target lesions.
Partial response: at least a 30% decrease in the sum of the LDs of target lesions.
Stable disease: not qualifying as either partial response or progressive disease, plus persistence of at least 1 non-target lesion.
Progressive disease: at least a 20% increase in the sum of the LDs of target lesions, clear progression of non-target lesions, and appearance of new lesions.

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. Idronoxil also activates the immune system, increasing the activity of human natural killer cells.

NOX66 is a first-in-class anti-drug with dual cytotoxic and immunological functions.

About Noxopharm
Noxopharm is an Australian drug development company with offices in Sydney and Hong Kong. The Company has a primary focus on the development of drugs to address the problem of drug- and radio-resistance in cancer cells, the major hurdles 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 that are held by subsidiary company, Nyrada, Inc.

Investor & Corporate Enquiries:
Prue Kelly
M: 0459 022 445
E: info@noxopharm.com

Company Secretary:
David Franks
T: +61 2 9299 9690
E: dfranks@fa.com.au

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.