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ASX Limited
20 Bridge Street
SYDNEY NSW 2000

ASX: NOX

Noxopharm Limited

ABN 50 608 966 123

Registered Office:
Suite 1 Level 6
50 Queen St
Melbourne VIC 3000
Australia

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

Positive clinical outcomes for NOX66 reported at ESMO conference

- **Patients with late-stage, metastatic cancers**
- **NOX66 in combination with carboplatin**
- **No toxicity associated with NOX66**
- **Stabilisation of disease process**

Sydney, 12 September 2017: Noxopharm (NOX: ASX) presented clinical data from its first-in-human clinical study of NOX66 to the European Society of Medical Oncology Annual Conference in Madrid (Spain) on 11th September 2017.

The data is in the form of a conference poster which is available at the following link:

http://www.noxopharm.com/irm/content/publications.aspx?RID=487

The Phase 1a/1b study involves patients with late-stage (Stage 4) metastatic cancer (lung, breast, prostate, ovarian, head and neck) who have failed standard treatments (chemotherapy and/or radiotherapy). Patients must have measurable lesions (lesions whose size is measurable on CT scan). The study has recruited 15 of planned 16 patients.

Patients are divided into 2 cohorts of 8 patients each. Cohort 1 receives 400 mg NOX66 daily and Cohort 2 800 mg daily. Each cohort has a 2-week run-in (Phase 1a) arm of NOX66 therapy alone; then in combination with carboplatin over 6 (monthly) treatment cycles starting with a low dose of carboplatin (AUC = 4) for 3 cycles (3 months), followed by a standard dose (AUC = 6) for the next 3 cycles (3 months). The total duration of treatment is 7 months.

So far, NOX66 has been well tolerated at both 400 and 800 mg dosages, both as a monotherapy and in combination with low- and standard-dosages of carboplatin. No side-effects have been ascribed to the use of NOX66.

Patients undergo a CT scan prior to treatment, and then on completion of each 3-months of combination treatment. Using RECIST criteria, patients are deemed to have undergone disease progression, or stable disease, or partial remission, or complete remission. Five patients have

completed 3-months treatment with low-dose NOX66 (400 mg) and low-dose carboplatin and been evaluated for disease status. Only 1 patient (lung cancer) showed progressive disease; 4 other patients (1x lung, 3x breast) showed stable disease; 1 of the latter patients continued to show stable disease after a further 3 months of standard-dose carboplatin therapy.

Noxopharm CEO, Dr Graham Kelly, said, "This is encouraging data. It's early days, but it needs to be remembered that this trial is using patients with late-stage cancers that have stopped responding to standard therapies. The data is from patients receiving the lower dose of NOX66 and a dose of carboplatin that is half of what would be used normally and which would not be expected to deliver any meaningful anti-cancer effect. Despite this, 4/5 patients have shown no disease progression."

Noxopharm is developing NOX66 as a sensitiser of standard cancer therapies. The Company sees 3 potential uses of NOX66 as a sensitiser:

- first, to increase response rates (more patients responding across most forms of cancer) to standard therapies;
- second, to achieve better response rates, but at lower dosages of chemotherapy and radiotherapy that will mean cancer therapy with fewer side-effects;
- third, to achieve an abscopal response (to radiotherapy only, where radiation of selected tumours leads to remission of both irradiated and non-irradiated tumours).

Ian Minns, Noxopharm Director of Medical Affairs and Clinical Development, said, "The data reported today is the lowest of 4 dosage combinations and we have yet to see the effect of the higher dosage of NOX66. But this preliminary data gives us the confidence to proceed into the next phase where we will be looking at the use of NOX66 in combination with radiotherapy alone or radiotherapy in combination with standard chemotherapy. This broad-ranging clinical trial program has been designed to help us decide the optimal way to look to obtain marketing approval for NOX66."

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About RECIST

RECIST is Response Evaluation Criteria in Solid Tumors. It is a standard way of assessing an anti-cancer response to therapy using CT and MRI. Lesions are characterized as either 'measurable' (>20 mm diameter) or 'non-measurable' (<20 mm diameter). A baseline assessment is made of all measurable lesions up to a maximum of five lesions per organ and 10 lesions in total. A partial response (PR) is defined as at least a 30% decrease in the sum of the diameters of measurable lesions; progressive disease (PD) is at least 20% increase in the sum of diameters of measurable tumours plus enlargement of non-measurable lesions; stable disease is neither PD nor PR.

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.

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

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