Date: 5 April 2018 **Sydney, Australia**

ASX: NOX

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DARRT-1 CLINICAL STUDY COMMENCES

- **Multi-national study testing ability of NOX66 to enhance radiotherapy**
- **First cohort of patients treated**
- **Direct and abscopal responses being evaluated**

Sydney, 5 April 2018: Noxopharm (ASX: NOX) today announces that the first cohort of 4 patients has commenced treatment in the Company's key DARRT-1 clinical study.

The DARRT-1 study is being conducted at 11 centres in Australia, New Zealand and Georgia. It involves men with late-stage prostate cancer (metastatic, castrate-resistant disease) receiving NOX66 in combination with a palliative (low) dose of radiotherapy. The first four patients have been recruited in Australia (1) and Georgia (3).

Patients with late-stage prostate cancer that have failed to respond to standard therapies typically have multiple secondary tumours in their skeleton and soft tissues such as lymph nodes. Radiotherapy often is used in an attempt to achieve relief from symptoms such as pain or spinal compression by irradiating a small number (1-3) of the largest tumours. Such treatment is referred to as *palliative treatment* because it is intended to provide symptomatic relief and not to be curative.

The rationale behind the DARRT-1 study, and the development of NOX66 in combination with radiotherapy, is that NOX66 potentially will enhance the anti-cancer effect of the radiation in two ways: first, that those tumours exposed to direct radiation will respond better and for longer; second, that all remaining tumours not exposed to radiation also will shrink (so-called *abscopal response*). The abscopal response is a rare phenomenon and would not be expected in these patients.

DARRT-1 involves exposing between 1 and 3 individual tumours to external beam radiotherapy, daily for 5 days. NOX66 is given daily for up to 15 days. The treatment is completed within 2 weeks; tumour response is assessed by scans after 6, 12 and 24 weeks. Side effects of treatment will be monitored throughout.

The study involves 24 men divided into 4 cohorts. The protocol calls for the first cohort of 4 men to undergo treatment with the lowest daily dosage (400 mg) of NOX66 as a safety review. If that treatment is well tolerated, as the Company anticipates, then the study will recruit a further 4 patients to receive 800 mg NOX66 (Cohort 2) , followed by a further patients to receive 1200 mg NOX66 (Cohort 3). The dose for the remaining 12 patients (Cohort 4) will be decided based on the review of the first 12 patients after all have been assessed at 6 weeks. It is anticipated that this milestone will be met in July 2018, with the remaining patients recruited into the study by August 2018.

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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 enhances tumour immunity by increasing the activity of human NK cells.

About DARRT Program

The DARRT program is Direct and Abscopal Response to Radiotherapy. It relates to the use of NOX66 to enhance the known abilities of radiotherapy both to kill cancer cells directly exposed to radiation (direct response), and to result in the death of cancer cells outside of the field of radiation (abscopal response). DARRT-1 involves men with metastatic castrate-resistant prostate cancer. Leter studies in this program will be conducted in patients with other forms of cancer, including rare and uncommon cancers.

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 sensitise cancer cells to radiotherapy and chemotherapy. NOX66 is the first pipeline product, with later generation drug candidates under development.

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Forward Looking Statements

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