

Date: 9 July 2018 Sydney, Australia

**ASX: NOX** 

ASX Limited 20 Bridge Street SYDNEY NSW 2000

**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

# RELEASE OF DARRT-1 PRELIMINARY SAFETY DATA AT CLINICAL CONFERENCE

**Sydney, 9 July 2018:** Noxopharm (ASX: NOX) today announces presentation of a poster concerning its DARRT-1 clinical study to the Annual Scientific Meeting of the Australia and New Zealand Urogenital and Prostate Cancer (ANZUP) Clinical Trials Group being held in Sydney.

The presentation discusses the design of the DARRT-1 Phase 1b study, along with interim safety data.

DARRT-1 is being conducted in men with late-stage prostate cancer (metastatic castrate-resistant) that is eligible for palliative radiotherapy for symptomatic relief. The experimental anti-cancer drug, NOX66, is being added to the palliative radiotherapy with the aim of achieving greater clinical response to the radiotherapy.

The study involves 24 men divided into 4 cohorts. The first 3 cohorts involve a NOX66 dose-finding study, each comprising 4 men (400, 800 and 1200 mg NOX66 respectively). The 4<sup>th</sup> cohort (12 men) will use the dosage of NOX66 considered to

be optimal.

NOX66 previously has shown to be well tolerated when used on its own or in combination with chemotherapy (carboplatin). However, the safety of NOX66 in combination with radiotherapy remained to be tested, in particular whether the drug, in seeking to enhance the killing effect of radiation on cancer cells, would at the same time increase the risk of radiation sickness.

The data reported today is from 9 patients (8 patients in Cohorts 1 and 2; one patient in Cohort 3). Three adverse events have been reported (dry mouth, mucositis oral, fatigue) from these 9 patients, all Grade 1 (mild) and defined as 'possibly related' to NOX66 therapy. This outcome suggests that a treatment course comprising 7 days of radiotherapy (20 Gy) and 15 days of NOX66 therapy (400 and 800 mg) is free from the risk of enhanced radiation sickness.

Clinical response (PSA levels, pain score, CT scans) is being assessed at 6, 12 and 24 weeks. The Company anticipates that the 12- and 24-week data will be the most reliable indicators of clinical response. Accordingly, it will release the 12-week data for Cohorts 1-3 as soon as they are available.

The poster will be available today on the **News: Publications** section of (www.noxopharm.com)

•••••

#### **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 is an immuno-oncology drug, increasing the activity of human mononuclear cells including NK cells.

#### **About DARRT**

The Company's DARRT (Direct and Abscopal Response to Radiotherapy) Program aims to test the ability of NOX66 to increase tumour response to palliative dosages of radiation, both external beam radiotherapy and stereotactic radiotherapy. DARRT patients are those with late-stage cancer that has metastasized, where palliative radiotherapy is being applied to between 1-3 separate tumours to provide relief from symptoms such as pain. The radiotherapy is being applied in fractionated dosages over 1-2 weeks, and the NOX66 administered daily over the course of radiotherapy + 1 additional week.

Two outcomes are being sought: the first is more complete response in the irradiated tumours (direct response); the second is a response in non-irradiated tumours (abscopal response).

#### **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.

**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.