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END OF YEAR GUIDANCE ON NOX66 CLINICAL DEVELOPMENT STRATEGY FOR 2018

- **3 current Phase 1 studies**
- **4 multinational Phase 2/Phase 3 DARRT studies in 2018**
- **Aim to identify nature of Phase 3 studies by 3Q 2018**
- **Data reports scheduled for international cancer conferences throughout 2018**
- **Commitment to brain cancer study in 2018, including treatment of secondary brain cancers**
- **Abscopal Research Unit established.**

Sydney, 21 December 2017: Noxopharm Limited (NOX:ASX) is pleased to provide guidance to the market on its clinical development strategy and indicative timetable for release of data in relation to its frontline drug candidate, NOX66.

A. Overall objectives

Under its DARRT (Direct and Abscopal Response to Radiotherapy) program, the Company's primary goal is to develop NOX66 as a first-in-class drug that will enhance the response of solid (both common and rare) cancers to radiotherapy. The objectives are (a) to allow lower dosages of radiotherapy to be administered, (b) to increase the anti-cancer effect in tumours directly exposed to radiotherapy, and (c) to induce a response in tumours not exposed to radiotherapy (abscopal response).

The aim is to improve radiotherapy outcomes in both adult and paediatric patients with most forms of solid cancers including cancers of the brain.

A secondary goal is to develop NOX66 as a first-in-class sensitiser of chemotherapy (e.g. carboplatin), with a combination of NOX66 and low-dose carboplatin to be used on a salvage basis in patients with late-stage, chemo-refractory solid cancers, to deliver a meaningful anti-cancer effect in a well-tolerated manner. The aim is to enhance the effect of standard chemotherapies, providing outcomes for patients at least equal to the level seen with newer agents such as immuno-oncology drugs in a cost-effective and well-tolerated manner.

B. Timetable

The aim with the DARRT program is to have a range of proof-of-principle studies running by mid-2018, with continuous assessment of data allowing the likely form of a Phase 3 registration study (or studies) to be identified by end of 3Q 2018. A multi-national Phase 3 registration study (studies) then commencing patient recruitment in 1Q/2Q 2019.

The strategy is to run a range of clinical studies across a range of different tumour types and treatment options (external beam radiotherapy, brachytherapy radiotherapy), (a) to maximise the likelihood of identifying the optimal route to market approval, and (b) to create the opportunity to seek Orphan Drug designation for a meaningful clinical effect in less common and rare cancers.

C. Specific study details

1. Current studies

1.1 NOX66 + chemotherapy

This is the Company's first-in-human study of NOX66. It is being conducted in Georgia in FDA-audited clinics in patients with late-stage solid cancers with no remaining standard treatment options. The study is fully recruited (19 patients) with the final patient completing treatment in April 2018. The design is a 4-way matrix of 2 dosages of NOX66 and 2 dosages of carboplatin (low and standard dosages).

The Company recently (18th November 2017) reported interim results for the study. The data showed that for 11 patients who had completed 3 months of treatment with NOX66 (either dosage) and low-dose carboplatin, only 1 of the 11 patients had shown disease progression, 9 showed no progression, and 1 showed a partial response (>30% reduction). The Company views these interim findings in patients with late-stage disease as highly encouraging, and supportive of the continued development plans.

The safety and efficacy data on all 19 patients after their 3-month treatment with low-dose carboplatin will be presented at an international cancer conference in March 2018, and final data (NOX66 + low-dose and standard-dose carboplatin) at an international cancer conference in June 2018.

A medical advisory board of international oncologists is being convened in Q2 2018 to advise on the design of a Phase 2/Phase 3 adaptive design study targeted to commence in Q4 2018.

1.2 NOX66 + brachytherapy (LUPIN Study)

This investigator-led Phase 1 study is underway at St Vincent's Hospital, Sydney. It is studying the safety and efficacy of NOX66 as a sensitiser of brachytherapy radiotherapy in men with metastatic castrate-resistant prostate cancer. The brachytherapy is ^{177}lutetium-PSMA-617 peptide. This intravenously-administered radiotherapy has proved promising in the treatment of men with late-stage disease, but is in need of an enhanced response both in terms of the proportion of responders and the duration of response. NOX66 is being tested for its ability to provide that enhanced response.

The study currently has 3 patients receiving monthly cycles of combination treatment. A safety review will be conducted after 4 patients have completed 2 monthly cycles. If well tolerated, the study will proceed to recruit the remaining patients. A minimum of 16 patients will be enrolled into this trial.

This study is expected to continue until the end of 2018, with data to be released at the discretion of the investigator. The Company expects to make a decision on progressing this opportunity into a Company-sponsored Phase 3 registration study in about mid-2018.

1.3 NOX66 + External Beam Radiotherapy (DARRT 1)

This is a multi-national Phase 1 open label study in 24 men with metastatic castrate-resistant prostate cancer. Between 1-2 tumours receiving palliative dosage of radiotherapy in conjunction with NOX66, with assessment of response of both irradiated and non-irradiated tumours made at 3 and 6 months.

First Australian centre now open for recruitment with an additional 4 Australian sites to open in 1Q 2018. Additional centres in New Zealand and Georgia also to open late-1Q 2018.

The Company anticipates reporting interim data (6-week review) at a conference in March 2018, with 3-month follow up of the first 12 patients in June 2018, and 6-month follow-up of all 24 patients in Q4 2018.

2. Future studies

2.1 DARRT 2, DARRT 3, DARRT 4, DARRT 5

These are 4 parallel studies, each with the same essential design features and study objectives. As with DARRT 1, patients will have multiple secondary tumours with between 1 and 2 of the tumours being exposed to a palliative dosage of external beam radiotherapy in the presence of NOX66. Depending on the number of lesions being irradiated, the treatment course will be 2-3 weeks.

- DARRT 2 will be in patients with metastatic castrate-resistant prostate cancer.
- DARRT 3 will be in patients with breast cancer.
- DARRT 4 will be in patients with lung cancer.
- DARRT 5 will be in patients with rare and less common cancers.

DARRT 2, 3 and 4 will use a Phase 2/Phase 3 adaptive design. Twelve patients will be enrolled in each study to begin with and their data reviewed early. Depending on the strength of the clinical signals, each study then will either be converted into a Phase 3 registration study, or continue as a Phase 2 study to provide additional data.

DARRT 5 is being undertaken to provide supportive data for registration purposes, including the ability to seek Orphan designation for specific rare cancer types. DARRT 5 will be open to patients with secondary brain cancer.

Planning for these 4 studies (site selection, study design) has commenced. The Phase 2 'sighting' component of each study will be conducted in Australia, New Zealand and selected eastern European (non-EU) countries with the aim of patient enrolment commencing by mid-2018. The Phase 3 extensions of each study will include centres in Western Europe, USA, China and other Asian countries.

D. Brain cancer

The confirmed ability of NOX66 to cross the blood-brain barrier in mice and rats has led the Company to initiate a major R&D program intended to bring NOX66 into the clinic in late-2018 as sensitiser of radiotherapy to treat brain cancer. In collaboration with a number of Australian research institutions, Noxopharm is working to confirm the utility of NOX66 in allowing palliative radiotherapy to treat primary brain cancers in adults (glioblastoma multiforme) and children (diffuse intrinsic pontine glioma), as well as secondary brain cancers in adults (breast, lung etc).

E. Abscopal response

The Company is establishing a dedicated Abscopal Response R&D Unit in the expectation of NOX66 proving to be a first-in-class facilitator of this rare phenomenon. The Unit will be comprised of experienced scientists in the fields of genomics and epigenetics who will work with clinical material in the DARRT program to seek to identify the underlying abscopal response mechanism and likely responders.

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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 prosurvival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapies.

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. NOX66 is the first pipeline product, with later generation drug candidates under development.

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