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DARRT-1 STUDY ADVANCING ON BASIS OF POSITIVE CLINICAL DATA

- **Trial to enrol final 12 patients at 1200mg dose**
- **Based on positive safety and clinical response data**
- **Next scheduled review late-January 2019**

SYDNEY, December 11, 2018: Noxopharm (ASX: NOX) announces that the Company's DARRT-1 clinical study has been approved to move to its final stage, with enrollment of the final 12 patients at a Veyonda® dosage of 1200 mg.

The first stage, now fully enrolled, was a dose-finding study to establish the therapeutic dosage of Veyonda® (400, 800 or 1200 mg). A committee comprising 2 independent medical monitors and all study investigators with patients enrolled in the study, reviewed the first 3 dosage cohorts on the basis of the following end-points:

Safety: blood chemistry, ECG, adverse events/serious adverse events.

Efficacy: scans (RECIST), PSA response, pain scores, Quality of Life (ECOG Score).

All 3 dose levels of Veyonda® in combination with radiotherapy were well tolerated and without any reported safety issues. Signs of positive clinical responses with the two highest dosages of Veyonda® (800 and 1200 mg) included partial responses, declines in PSA greater than 50%, and material reductions in pain scores.

Greg van Wyk MD, Noxopharm Chief Medical Officer, said, "The DARRT program aims to provide meaningful clinical and quality of life benefits for men with end-stage prostate cancer using a treatment regimen that is just 3 weeks long, minimally invasive, and well tolerated. Currently these men have no approved therapy options. And while any assistance for these men would be worthwhile, even if it just to relieve debilitating bone pain, the clinical responses we are seeing already suggests that Veyonda® is capable of delivering a considerably greater clinical benefit."

"The DARRT-1 study is meant to inform the design of the Company's upcoming registration study for Veyonda®. End-points acceptable to regulators such as the FDA can range from providing better quality of life via, for example, pain reduction, through to better survival outcomes. We are hopeful of achieving both outcomes, but strategically we want to identify the best end-point that will allow the program to advance as rapidly as possible," van Wyk said.

Patients are reviewed at 6, 12 and 24 weeks post-treatment. The current review was conducted on all Cohort 1, 2 and 3 participants and included some patients who have only reached their 6 week review point. All patients will have completed 12 weeks post-treatment at the end of January 2019 and that data will provide a better view of the depth and durability of the response. The Company expects to

release that data to the market shortly after that. It also plans on submitting that data to a major international cancer conference.

The DARRT-1 program is being developed as a potentially transformative approach to the management of men with late-stage, metastatic, castrate-resistant prostate cancer. DARRT-1 trial participants have progressive disease with no remaining standard treatment options. Typically, such men have bone metastases causing significant pain.

The DARRT regimen involves exposing a single tumour (primary or secondary) to a low dose of external beam radiotherapy (approximately one-third of a standard dose) in combination with Veyonda® treatment. Veyonda®, as a cancer-specific radio-enhancer, aims to boost the cancer-killing effect of the radiation on the exposed tumour(s), at the same time stimulating the patient's innate immune system (natural killer cells). The objective is to trigger an immune response that leads to an anti-cancer outcome in both irradiated and non-irradiated tumours throughout the body.

The Company anticipates Veyonda® entering its final clinical step before the end of next year and currently is making all necessary preparations accordingly.

Graham Kelly Ph.D., Noxopharm CEO, said, "An estimated 30,000 men will die of prostate cancer in the US. alone this year, and new treatment approaches desperately are needed. We are taking a dual approach to the use of Veyonda® in the treatment of late-stage prostate cancer with our ongoing DARRT and LuPIN programs. Prostate cancer comes in multiple forms depending on which prostate gland cells are involved and the expression of different pro-cancer genes. For that reason, we expect it will be likely that we will end up needing to match one of these two treatments to each situation."

About Veyonda®

Veyonda® (previously known as 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, pre-eminent among which is sphingosine kinase, a key regulator of cell pro-survival mechanisms, and which is over-expressed in many cancer cells. Idronoxil also is an immuno-oncology drug, activating the body's innate immune system e.g. natural killer (NK) cells.

About DARRT-1

DARRT stands for Direct and Abscopal Response to RadioTherapy. It involved using Veyonda® to increase tumor response to palliative dosages of radiotherapy. The DARRT treatment regimen entails a 5-day course of radiotherapy (20-30 Gy) in 5 fractionated dosages targeting 1-2 larger tumors, and the Veyonda® administered daily for up to 3 weeks. The rationale of DARRT is to combine the radio-enhancing properties of Veyonda® that stem from its sphingosine kinase inhibition, with its ability to stimulate the body's first line immune defense cells against cancer. The clinical outcome being sought is greater shrinkage of irradiated tumors and shrinkage of all non-irradiated tumors (abscopal response).

End-points include scans to determine the size and number of lesions (RECIST = Response Evaluation Criteria in Solid Tumors), blood levels of PSA (Prostate Specific Antigen), a 0-10 Pain Score, and a 0-5 Quality of Life Performance Score (ECOG = Eastern Cooperative Oncology Performance Status).

About Noxopharm

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney, Hong Kong and New York. The Company has a primary focus on the development of drugs based on an isoflavonoid chemical structure. Veyonda® is the first pipeline product, with 3 other drug candidates for non-oncology indications under development in a subsidiary company (Nyrada Inc).

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Forward Looking Statements

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