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EVIDENCE OF ABSCOPAL RESPONSES IN PATIENTS

- **Presentation at national oncology conference includes first 2 patients treated compassionately with NOX66 + radiotherapy**
- **Abscopal responses obtained in both patients**
- **Data supports Noxopharm approach for use of NOX66 in cancer treatment.**

Sydney, 21 March 2018: Noxopharm (ASX: NOX) today presented a scientific update to the 30th Annual Scientific Meeting of the Trans Tasman Radiation Oncology Group (TROG), taking place in Hobart, Australia. As part of this update, two clinical cases – the first involving combination of NOX66 and radiotherapy – were presented. Both cases received NOX66 on a compassionate use outside of the Company's formal clinical trial program.

The case reports were presented by Professor Paul de Souza, Chairman of the Noxopharm Medical Advisory Board and detailed the patients' medical and treatment histories and clinical outcomes.

The two cases involved patients with late-stage, metastatic cancer who received NOX66 in combination with palliative (low dosage) radiotherapy – a similar regimen to that being used by Noxopharm in its DARRT (Direct and Abscopal Response to Radiotherapy) clinical development program.

Patients in the DARRT program are treated with a standard of care course of radiotherapy intended to be palliative (intended to reduce symptoms such as pain, but not expected to provide a significant or durable clinical response). NOX66 is administered in combination with the radiotherapy with the intention of enhancing the clinical benefit of the radiotherapy.

The rationale is that NOX66 at the very least will lead to greater and more durable shrinkage of the irradiated tumours, and at best to a similar response in all other tumours in the body that are not irradiated (so-called 'abscopal response').

Case 1. A 68-year old man with metastatic, castrate-resistant prostate cancer involving secondary tumours in bone and soft tissue. The patient required palliative radiotherapy of a vertebral lesion causing spinal compression and paralysis, and enlarged pelvic lymph nodes causing pain. These 2 tumours were treated directly with radiotherapy and NOX66 was administered throughout the course of radiotherapy. At 2-months following treatment, scans showed complete disappearance of the irradiated tumours and the absence of any other visible tumours in the body; PSA levels (a blood

marker of prostate cancer load) also were returning to normal. The patient remains 3.8 years later in complete remission with undetectable PSA levels and has required no further treatment in that time. This case meets the definition of a complete abscopal response.

Case 2. A 70-year old woman with leiomyosarcoma (cancer of smooth muscle cells) arising in the wall of the body's largest vein (inferior vena cava), with multiple secondaries in the lung causing the patient to have a chronic cough. The patient was not considered suitable for any curative treatment at the time of diagnosis and underwent initial treatment with NOX66 in combination with a standard chemotherapy (doxorubicin). This treatment had no effect, with a slight increase in the size of the lung metastases being observed. Subsequently, the patient underwent a course of palliative radiotherapy to the primary tumour in the presence of NOX66. Within 1 month of treatment, a significant reduction in the size of the lung metastases was observed, with the patient's cough resolving. Six months later, the primary tumour remains stable and the earlier response seen in the lung metastases remains. This case meets the definition of a partial abscopal response.

As part of the presentation, an overview of the DARRT-1 study was provided. The objective of this first-in-human clinical trial of NOX66 + palliative radiotherapy in patients with end-stage metastatic prostate cancer is to confirm the safety of the combination and to provide efficacy signals to guide the design of a larger study.

Graham Kelly, Noxopharm CEO, said, "Both of the patients presented in the case studies have shown a response to treatment at sites which were not subjected to direct radiation therapy – this is known as an abscopal response and is a very rare phenomenon. With 2 out of 2 patients with distinctly different cancer types responding in this way, we now are focused on continuing with our clinical development program to confirm this outcome in a larger number of patients. If all we are able to do is to provide a partial abscopal response in patients as we have seen in case study 2, we believe this would be a major advance in the treatment of late-stage metastatic cancer. Providing a complete abscopal response as seen in case study 1, potentially represents a new frontier in cancer therapy."

An abscopal response refers to a situation where radiation is applied to individual tumours in a highly discrete way, and leads to a response both in the irradiated tumours as well as tumours elsewhere in the body. The mechanism of action is unknown, with evidence both for an immune response (activation of immune cells) and an epigenetic response (release of chemical signals from damaged cancer cells instructing death of undamaged cancer cells). Idronoxil has unique triple action anti-cancer effects: (i) directly cytotoxic (killing) to cancer cells; (ii) blocking the repair mechanisms that cancer cells use to repair radiation-induced cell damage; and (iii) increasing the activity of anti-tumour natural killer (NK) cells.

"We are undertaking a major clinical effort to explore the extent of the ability of NOX66 to induce an abscopal response. DARRT-1 is a Phase 1b study in 24 men with late-stage prostate cancer involving 11 sites in Australia, NZ and Georgia. The Company expects to be releasing the initial clinical data from this study by July 2018. DARRT-2 is in the planning stage and will be a Phase 2 study in upwards of 60-80 patients and involve a broad spectrum of solid cancers including rare cancers," Kelly added.

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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 increases the activity of human NK cells.

About Professor Paul de Souza

Professor Paul De Souza is Foundation Chair of Medical Oncology, School of Medicine, at Western Sydney University; a conjoint Professor in the Faculty of Medicine, UNSW; and an Honorary Professor at the NHMRC Clinical Trials Centre, The University of Sydney. He has over 20 years' experience in the care of patients with cancer.

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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