DARRT-2 Study Receives IND Approval from FDA

- **Multi-national DARRT-2 study receives Investigational New Drug (IND) approval by the FDA**
- **Second IND granted for use of Veyonda® in U.S. cancer patients**
- **Two prominent US cancer centres have sought to participate, including the MD Anderson Cancer Center, the largest comprehensive cancer centre in the U.S.**
- **Total of up to 15 sites in Australia, France, Hungary and U.S.**
- **Testing combination of Veyonda and low-dose radiotherapy to induce abscopal anti-cancer responses in end-stage prostate, breast, lung cancers.**

Sydney 1 July 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted Investigational New Drug (IND) approval to the DARRT-2 study, allowing the study to start in the U.S.

DARRT-2 is a multi-national clinical study being conducted in up to 15 sites across Australia, France, Hungary and the U.S.

The University of Texas MD Anderson Cancer Center, the top-ranked cancer treatment centre in the U.S., along with the Beverly Hills Cancer Center in Los Angeles, have sought to be involved in the study and will serve as the U.S. sites.

DARRT combines Veyonda® with low-dose external beam radiotherapy (EBRT) delivered to an isolated tumour to trigger a whole-of-body anti-cancer outcome known as an *abscopal response*. The rationale is that low-dose EBRT activates a local immune/inflammatory response within the irradiated tumour that is amplified by Veyonda, converting a local anti-cancer response into a systemic response.

Ethics review currently is underway in Australia. Those sites and the timing of patient recruitment are expected to be announced very shortly.

As mentioned previously (*ASX: 10 June 2021*), DARRT-2 will involve approximately 100 patients with progressive, metastatic cancers whose cancers have failed standard treatment options and who are eligible for low-dose, palliative external beam radiotherapy. The cancers will be mainly prostate cancer, with a smaller cohort of breast or lung cancer.

The international clinical research organisation, Parexel, is facilitating the study.

Dr Gisela Mautner, Noxopharm Chief Medical Officer, said, "This is the second IND granted by the FDA for Veyonda and is an endorsement of our concept of seeing Veyonda become a companion treatment for other standard cancer treatments.

FDA approval for the DARRT-2 study is a major step forward in our endeavour to expand access of American cancer patients to Veyonda. The interest of the MD Anderson Cancer Center, one of the top cancer centres in the U.S., is something we are very proud of. This will give our study a huge boost. Clearly, these achievements demonstrate that we have an excellent team in place that is highly competent and motivated to deliver results for patients, and for the Company".

Dr Chad Tang, Assistant Professor and Radiation Oncologist at the MD Anderson Cancer Center, said, "I am very excited to be the lead investigator at MD Anderson for this interesting trial. It will be an important study for patients with metastatic cancer who require low-dose radiation therapy."

About DARRT

DARRT stands for Direct and Abscopal Response to Radiotherapy. It involves the application of low-dose (8, 20 or 25 Gy) external beam radiotherapy in 1-5 fractionated doses to a tumour. Veyonda is administered daily for 7-14 days in repeated cycles.

DARRT-2 builds on the encouraging safety and efficacy data from DARRT-1 but expanding into higher dosages of Veyonda (potentially up to 2400 mg daily), repeat cycles of Veyonda, and three different cancer types (prostate, breast, lung). Endpoints will be safety and tolerability, as well as clinical measures of efficacy such as tumour size changes, time until disease progression, health-related quality of life measurements, and overall survival.

About Noxopharm

Noxopharm Limited (ASX:NOX) is an Australian clinical-stage drug development company focused on the treatment of cancer and cytokine release syndrome (septic shock).

Veyonda® is the Company's first pipe-line drug candidate currently in Phase 2 clinical trialling. Veyonda® has two main drug actions – a moderating effect on the ceramide/sphingosine-1-phosphate balance and inhibition of STING signalling. Activity against the former target contributes to its dual-acting oncotoxic and immunomodulatory functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiation therapies and immune checkpoint inhibitors. Activity against the latter target provides an anti-inflammatory effect, also contributing to an anti-cancer action, but also potentially blocking cytokine release syndrome.

Noxopharm also has drug discovery programs running in both oncology and inflammation, and is the major shareholder of US biotechnology company, Nyrada Inc (ASX:NYR), active in the areas of drug development for cardiovascular and neurological diseases.

To learn more, please visit: noxopharm.com

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Graham Kelly, CEO and Managing Director of Noxopharm, has approved the release of this document to the market on behalf of the Board of Directors

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Forward Looking Statements

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