Noxopharm Limited (ASX:NOX) | ASX Announcement | 4 November 2021

DARRT-2 Trial Commences in the U.S.

Highlights

- **First patients enrolled in multi-national DARRT-2 trial testing potential ground-breaking immunotherapy involving Veyonda® and low-dose external beam radiotherapy**
- **DARRT-2 builds on success of DARRT-1 with more intense Veyonda® treatment**
- **Interim data expected 2022**
- **Joins IONIC-1 and soon to start CEP-2 trial as proof-of-concept trials designed to position Veyonda® as a standard means of enhancing the effectiveness of the most common forms of cancer treatments**

Sydney 4 November 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to announce that its DARRT-2 Phase 2 clinical trial has commenced with patient enrolment in the U.S.

DARRT (Direct and Abscopal Response to Radiotherapy) is an experimental immunotherapy cancer treatment based on the concept of Veyonda® combining with well tolerated, low dosage of external beam radiotherapy to trigger an immune response, leading to the resolution of some or all tumours in the body. This form of immune response is known as an *abscopal response*.

Noxopharm believes that DARRT-treatment has the potential to revolutionise cancer treatment by achieving cancer reduction through the abscopal response without many of the unwanted side-effects, cost-limitations, and logistical challenges associated with other immunotherapies.

With low-dose (palliative) radiotherapy being a common form of therapy used in cancer care, the therapeutic and commercial opportunities of adding Veyonda to transform symptomatic relief into a meaningful tumour response are substantial. The Company is confident of securing the value of this opportunity by patents, starting with the allowance of claims by the U.S. Patent Office as previously announced (*ASX: 27th September 2021*).

Also as previously announced (*ASX: 10 Jun 2021, 1 Jul 2021*), DARRT-2 is being undertaken across multiple sites in North America, Europe, and Australia involving approximately 100 patients with metastatic cancers (prostate, breast, lung) who are eligible for palliative radiotherapy.

The inaugural sites in the U.S. are the prestigious Beverly Hills Cancer Center in Los Angeles and the University of Texas's MD Anderson Cancer Center, one of the largest cancer treatment centres in the world and consistently rated one of the best cancer treatment centres in the U.S.

The FDA granted an IND approval for the DARRT trial treatment (*ASX Announcement 1 July 2021*).

Noxopharm Chief Medical Officer, Dr Gisela Mautner, said, *"The participation of prestigious institutions with their highly experienced radiation and medical oncologists is testament to the interest in and potential of the DARRT-treatment.*

More sites will come online progressively over the next few months and accelerate patient recruitment. We will keep the market updated as the study progresses."

-ENDS-

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.

About DARRT

DARRT stands for Direct and Abscopal Response to Radiotherapy. It involves the application of low-dose (up to 25 Gy) external beam radiotherapy in 1-5 fractionated doses to a single tumour in a single treatment cycle. Veyonda is administered daily for up to 14 days in conjunction with the single radiotherapy cycle, and then in repeated monthly cycles without radiotherapy.

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.

The aim of DARRT is to use idronoxil, the active ingredient in Veyonda, (i) to augment radiation-induced damage of both nuclear and mitochondrial DNA damage, and (ii) to prevent repair of that damaged DNA, thereby triggering an interferon-led local immune response that becomes systemic.

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/TBK1 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, as well as contributing to an anti-cancer action, but also potentially blocking septic shock.

Noxopharm is running comprehensive drug discovery programs 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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statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company's control (including but not limited to the COVID-19 pandemic) that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement.