DARRT-2 Trial Passes Safety Milestone and European Trial Site Activated

Highlights

- **DARRT-2 gains momentum with safety milestone reached and additional trial site**
- **Safety Steering Committee finds Veyonda® dosage safe in combination with external beam radiotherapy for a range of cancers**
- **Trial now underway across three continents as first European site is activated**

Sydney 2 August 2022: Innovative Australian biotech **Noxopharm Limited (ASX:NOX)** announces the DARRT-2 Safety Steering Committee has reviewed the safety data from the second cohort of patients from the dose escalation part of the DARRT-2 trial.

The dose was found to be safe and well tolerated, enabling the trial to advance to enrol patients into a third cohort with an increased dose level.

The DARRT-2 Phase 2 trial is evaluating Noxopharm's clinical drug candidate Veyonda® in combination with external beam radiotherapy for the treatment of prostate, breast and lung cancer.

The second dose cohort of patients in the trial was treated with 1200 mg of Veyonda, and the dose was found to be safe and well tolerated. Approval has been given to progress the study, and therefore treatment of the third cohort of patients with a 1600 mg dose of Veyonda will now commence.

Additionally, a new DARRT-2 trial site in Hungary is now active and will soon begin enrolling patients. The DARRT-2 trial has been authorised to proceed by major regulatory bodies in the US, Europe and Australia, and is now open for enrolment across three continents.

The Hungarian site joins, among others, two prestigious hospitals in the US; the Beverly Hills Cancer Center in Los Angeles, and the renowned MD Anderson Cancer Center in Houston, one of the largest cancer hospitals in the world and consistently rated one of the best cancer treatment centres in the country. Active enrolment is also underway in Sydney, Australia (announced 14 December 2021).

Noxopharm CEO Dr Gisela Mautner stated: "The DARRT-2 trial continues to gain momentum as we have passed another significant milestone with a positive safety data review, and we are now recruiting patients in leading cancer hospitals across three continents. We will keep the market updated as this trial progresses."

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About DARRT
DARRT is a Phase 1b/2a dose expansion, dose escalation clinical trial in patients with metastatic cancers across multiple sites in the US, Europe and Australia. The trial is examining the combination of Veyonda with low-dose radiotherapy for the treatment of prostate, breast and lung cancer.

Veyonda is combined with 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.

Data generated to date in the DARRT-1 trial has shown a good safety profile and encouraging efficacy signals with good tumour control and improvements in relevant biochemical markers and reduced pain in patients with advanced metastatic prostate cancer. DARRT-2 builds on the encouraging safety and efficacy data from DARRT-1 and expands into higher doses 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 innovative Australian biotech company discovering and developing novel treatments for cancer and inflammation.

It has three active drug development programs: its clinical drug candidate Veyonda®, plus two innovative technology platforms, Chroma™ and Sofra™ which provide the basis for active development of a growing pipeline of new proprietary drugs in cancer, inflammation, and autoimmunity.

Noxopharm also has a major shareholding in the US biotech company Nyrada Inc (ASX:NYR), which is active in the areas of drug development for cardiovascular and neurological diseases.

To learn more, please visit: noxopharm.com

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Dr Gisela Mautner, CEO and Managing Director of Noxopharm, has approved the release of this document to the market on behalf of the Board of Directors.

Forward Looking Statements

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as “aim”, “anticipate”, “assume”, “believe”, “continue”, “could”, “estimate”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “plan”, “should”, “target”, “will” or “would” or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking 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.