



## CEP-2 Safety Milestone Shows Veyonda® Progress

### Highlights

- **CEP-2 sarcoma trial passes second safety milestone**
- **Safety Steering Committee finds Veyonda® dosage safe in combination with chemotherapy drug doxorubicin**
- **Northwestern University in Illinois and the Medical College of Wisconsin added as trial continues in prestigious US hospitals**

**Sydney 16 November 2022:** Innovative Australian biotech **Noxopharm Limited (ASX:NOX)** announces the CEP-2 Safety Steering Committee has reviewed the safety data from the second cohort of patients in the trial.

The 1200 mg dose was found to be safe and well tolerated, allowing enrolment to continue with the next patient cohort to be treated with an increased Veyonda® dose of 1800 mg. This will be the last dose cohort for the safety phase of this study, and if tolerated satisfactorily, will pave the way for the efficacy phase to begin.

The CEP-2 Phase 1 trial is evaluating Noxopharm's clinical drug candidate Veyonda in combination with the chemotherapy drug doxorubicin as a first-line treatment of soft tissue sarcoma.

In order to speed up patient enrolment, two new sites have also been added to the trial, which is underway in several prestigious hospitals in the US. Northwestern University in Illinois and the Medical College of Wisconsin join other prominent names already participating in the trial, including the City of Hope Cancer Center in Los Angeles, Mayo Clinic (Minnesota and Florida sites), and Washington University in St. Louis.

Noxopharm CEO Dr Gisela Mautner stated: "After recently passing the first safety milestone in August, the CEP-2 trial has passed its second safety milestone and we are now able to escalate to the highest dose of Veyonda ever trialled in cancer patients."

"These safety reviews form a crucial part of the regulatory requirements for a new drug, and only through positive safety outcomes can we move forward to the next stage. We are also pleased to bring on two additional major US clinical centres, and will continue to work closely with our partners to advance these trials as quickly as possible."

**-ENDS-**

## **About CEP-2**

CEP-2 is a Phase 1, open-label, dose-escalation and dose-expansion study of Veyonda® administered to cohorts of patients being treated with doxorubicin for the treatment of metastatic soft tissue sarcoma.

Approximately 30 patients in the United States with a range of soft tissue sarcomas are being enrolled across six US sites to be treated with the Veyonda / doxorubicin combination as a first-line treatment.

Soft tissue sarcomas are generally very aggressive cancers. Up to 50% of high-grade sarcoma patients develop metastases and die within 12 months. They are defined as a rare cancer, with fewer than 20,000 new cases diagnosed in the US in 2021.

The CEP program is based on preclinical and clinical findings of Veyonda enhancing the anti-cancer effect of a number of standard chemotherapeutic agents. The findings from the CEP-1 clinical trial have been published in *Current Therapeutic Research* in April 2021. Veyonda has been granted US FDA Orphan Drug Designation (ODD) for the treatment of sarcoma. This confers a period of market exclusivity and a number of financial and regulatory benefits.

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## **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™ (oncology) and Sofra™ (inflammation and autoimmunity), which provide the basis for active development of a growing pipeline of new proprietary drugs.

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](http://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.*

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## **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



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