Orphan Drug Designation Granted to Noxopharm by US FDA

Highlights

- **United States FDA grants Orphan Drug Designation to Veyonda for use in treatment of soft tissue sarcoma**
- **Orphan Drug Designation confers a number of commercial advantages including tax credits and US market exclusivity**
- **CEP-2 soft tissue sarcoma trial is currently underway in the United States**

Sydney 22 March 2022: Innovative Australian biotech **Noxopharm Limited (ASX:NOX)** is pleased to announce that its lead oncology drug candidate Veyonda® has been granted Orphan Drug Designation (ODD) by the United States Food and Drug Administration (FDA) for its use in the treatment of soft tissue sarcoma.

The ODD program has been established by the FDA to encourage companies to develop treatments for less common disorders. The FDA grants *orphan status* to drugs that show promise to be a safe and effective treatment for diseases affecting fewer than 200,000 people per year in the USA. Receiving the ODD will speed up the Company's commercial development plan for the important US market.

An ODD confers the following benefits:

- Orphan Drug Exclusivity (ODE) provides seven years of market exclusivity
- Waiver of New Drug Application fees (value of approximately $2.9 million in 2021)
- Opportunities for grant funding from the Office of Orphan Products Development and
- Regulatory guidance and assistance from the FDA with the drug development process

Noxopharm CEO, Dr Gisela Mautner stated 'It is pleasing that the Noxopharm application for Orphan Drug Designation was approved so quickly. Considering that out of approximately 360 approved ODDs last year, only four went to Australian companies, demonstrates the high bar that is being set by the FDA. The 7-year period of market exclusivity is commercially extremely valuable, as it means that the FDA will not approve a subsequent drug for the same use within this timeframe.'

'The ODD will significantly increase the value proposition of Veyonda to potential purchasers or licensees by both lowering current development costs and by providing future competitive and financial advantages as Veyonda progresses through the clinical trial stages towards registration and approval for sale in the US. With the FDA orphan drug designation now secured for Veyonda, the Noxopharm team is excited to move our preclinical assets along the drug development process, while continuing to deliver on our clinical program plan.'

Noxopharm is currently conducting the CEP-2 trial into the treatment of soft tissue sarcoma in the United States (ASX Announcement 28 February 2022) and will keep the market informed as the study proceeds.

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About the CEP-2 Trial

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 to be treated with the Veyonda / doxorubicin combination as a first-line treatment. A number of major sites are participating in CEP-2. The first, the City of Hope Cancer Center in Los Angeles, has commenced treatment, with other sites to be activated shortly.

Soft tissue sarcomas are often fatal 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 pre-clinical 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.

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 lead clinical-stage drug candidate Veyonda®, plus two innovative technology platforms, 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

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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.