



21 February 2020

Sydney, Australia

## FDA grants IND approval to Veyonda®

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### Highlights

- Veyonda® granted IND for sarcoma patients
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**Sydney, 21 February 2020:** Noxopharm (NOX:ASX) announces today that the U.S. Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application for Veyonda® for combination treatment with doxorubicin in patients with soft tissue sarcomas.

Gisela Mautner, MD, PhD, Noxopharm CMO, said, “The IND approval, based on pre-clinical and clinical data presented to the FDA, is validation of the clinical potential of Veyonda®. In addition, Veyonda® has met the very high standard set by the FDA for being a safe and well-tolerated drug.”

Graham Kelly PhD, Noxopharm CEO, said, “Bringing Veyonda® to market for late-stage prostate cancer remains our commercial imperative. This IND grant for a less common cancer type contributes to that overall commercial objective in several ways. First, because the IND approval process has familiarised the FDA with Veyonda® ahead of IND applications for more advanced DARRT and LuPIN study submissions, and second because it opens the door to the use of Veyonda® in patients in the U.S. from where the Company increasingly is receiving patient enquiry.”

“This IND grant is just one step in our objective of achieving a strategic partnering arrangement. Immuno-oncology therapies are the current dominant area of development in the cancer field, with the particular need for therapies that restore immune function to tumours emerging as a prime area of global R&D and M&A activities. This follows the recent awareness of many human tumours being so-called cold, or devoid of immune function, limiting the effectiveness of current immuno-oncology drugs,” Kelly said. “Our growing pre-clinical and clinical data points to Veyonda® as a uniquely acting immuno-oncology drug candidate capable of meeting this need. The Company is actively positioning itself to take advantage of this opportunity.”

The IND approves a Phase 1b study involving a combination of Veyonda® and doxorubicin in adults with soft tissue sarcomas. The Company now proposes to explore available non-dilutive funding opportunities to enable the study to proceed.

**About Veyonda®**

Veyonda® is a suppository dosage form of idronoxil, a first-in-class inhibitor of sphingosine-1-phosphate (S1P). S1P is a key secondary messenger in cells, with dual roles of activating major pro-survival signalling pathways and regulating immune cell trafficking in tissues. Many solid cancers over-express S1P, supporting unregulated tumour growth and suppressing immune cell populations in tumours. By inhibiting the over-expression of S1P-driven pro-survival pathways, idronoxil is designed to sensitise cancer cells to the anti-cancer effects of drugs such as doxorubicin, as well as to radiation. By inhibiting the over-expression of S1P-driven exclusion of immune cells from tissues, idronoxil is designed to restore normal trafficking of immune cells.

**About Noxopharm**

Noxopharm is a clinical-stage Australian oncology drug development company with offices in Sydney and New York. The Company has a primary focus on the development of Veyonda® and is the major shareholder in the non-oncology drug development company, Nyrada Inc. (ASX:NYR).

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*Graham Kelly, CEO and Chairman of Noxopharm, has approved the release of this document to the market.*

**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 that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement.