FDA IND Approval Leads to Breakthrough Testing of Veyonda in First-Line Sarcoma Treatment

- Investigational New Drug (IND) granted by FDA on evidence that Veyonda may increase generally poor response rates of sarcoma cancers to chemotherapy
- Major success in approval to trial Veyonda as first-line treatment
- Study designed to provide proof-of-principle of ability of Veyonda to enhance chemotherapy
- Sarcoma deliberately selected as a rare cancer carrying important funding and regulatory approval benefits including 7-year exclusive marketing opportunities.

Sydney 7 May 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) announces that its CEP-2 study will open shortly.

As previously announced (*ASX: 21 Feb 2020*), the U.S. Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application for Veyonda® in combination with common chemotherapy drug, doxorubicin, for patients with soft tissue sarcomas. Today's announcement marks the Company's commitment to act on this valuable opportunity with the appointment of a contract research organisation to oversee the study.

Sarcomas have very limited treatment options with only an estimated 14% of soft tissue sarcomas responding to chemotherapy.[1] The Company is confident that Veyonda, with its unique mix of immunotherapy actions, has the means to change that by increasing both survival and response rates significantly when combined with the sarcoma standard of care drug, doxorubicin.

Why chemotherapy

- The ultimate aim is to establish Veyonda as a standard booster of all four major forms of cancer therapy – chemotherapy, external radiotherapy, internal radiotherapy, and checkpoint inhibitor therapy
- Each of those 4 sectors represents a major commercial opportunity, but collective success in 2 or more sectors stands to raise the potential industry value of Veyonda immeasurably
- The CEP-2 study, part of the Company's Chemotherapy Enhancement Program (CEP), is a key plank in that strategy, because after 50 years, chemotherapy still remains the backbone of cancer therapy, a position anticipated to continue for the foreseeable future with the global chemotherapy market widely predicted to reach US$50+ billion by 2024

- Based on its mechanisms of action, Noxopharm is confident that the majority of chemotherapy drugs in use today would benefit from being combined with Veyonda, thereby creating a multi-billion dollar drug opportunity in its own right.

However, there is an additional commercial imperative which is that the current market is dominated by drugs that either are off-patent or nearing the end of their patent life. Combining drugs with Veyonda to achieve greater anti-cancer potency offers the potential for renewed patent life, a highly prized outcome in the pharmaceutical industry. The Company has a patent application currently under examination that relates to the use of idronoxil (Veyonda active component) in combination with various chemotherapy drugs.

Why sarcoma

- The Company has selected **soft tissue sarcomas** as its proof-of-principle indication for demonstrating chemotherapy enhancement by Veyonda

- Sarcoma is a rare cancer, with an estimated 13,400 new cases to be diagnosed in the U.S. in 2021[2]

- Rare cancers offer important commercial incentives including Orphan Drug designation carrying valuable funding benefits/regulatory review benefits/7-year market exclusivities/extended patent life

- Little competition.

CEP-2

- CEP-2 builds on the encouraging outcomes of the CEP-1 pilot study where the chemo-enhancing effect of Veyonda was used to lower dosages of chemotherapy (carboplatin) in patients with advanced solid cancers (breast, ovarian, lung, prostate) (*ASX: 30 April 2021*)

- CEP-2 builds on that positive experience by using higher dosages of Veyonda (*expected to provide a greater chemo-enhancing effect*) and patients undergoing first-line treatment (*tumours expected to respond better to combination treatment*)

- CEP-2 is a Phase I study where approximately 40 patients with a range of soft tissue sarcomas will receive the Veyonda/doxorubicin combination as a first-line treatment

- Global clinical research organisation, Parexel® Biotech, has been engaged to oversee the study and site selection currently is underway in both the U.S. and Australia. The clinical protocol has been established and the study will start enrolling patients following site selection and ethics approvals

- The Company's strong cash position around a successful $23M capital raise in December 2020 means it can proceed with this study, although the Company continues to seek global sources of non-dilutive funding.

Dr Graham Kelly, Noxopharm CEO, said, "Soft tissue sarcomas are in that basket of cancers where there has been remarkably little advance in survival statistics over the past few decades, and the horizon looks to hold little change. What we have seen to date with Veyonda gives us confidence that a combination of Veyonda and doxorubicin has the capacity to make that change.

We want to see Veyonda eventually used as a standard companion drug in cancer therapy. That is behind the Company's 4-pillars oncology strategy of which the CEP program is a key part."

More details on the CEP-2 study will be shared as the project progresses.

This study is dedicated to the memory of Jennie Young, the second patient to receive Veyonda. Jennie Young had metastatic leiomyosarcoma that was considered by her doctors to have successfully responded to a Veyonda/doxorubicin combination when given on compassionate use grounds.[3] That experience, backed by considerable positive pre-clinical data,[4] forms the rationale for conducting this study.

References

1. Ratan R, Patel S. Chemotherapy for soft tissue sarcoma. Cancer (2016) 122, 2952-2960. https://doi.org/10.1002/cncr.30191
2. American Cancer Society
3. Noxopharm data. On file
4. Noxopharm data. On file

-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 Noxopharm

Noxopharm Limited (ASX:NOX) is an Australian clinical-stage drug development company focused on the treatment of cancer and 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 signalling. Activity against the former target contributes to its dual-acting oncotoxic and immuno-oncology functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiotherapy and immune checkpoint inhibitors. Activity against the latter target provides an anti-inflammatory effect, also contributing to an anti-cancer action, but also potentially blocking septic shock.

Noxopharm also is the major shareholder of US biotechnology company Nyrada Inc (ASX:NYR).

To learn more, please visit: noxopharm.com

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Forward Looking Statements

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