Noxopharm Awarded $8.8M Australian Government Grant for Sarcoma Trial

Highlights

- **$8.8M grant from the Australian Government's Medical Research Future Fund (MRFF) a major validation of Noxopharm science**
- **One of the largest grants of its kind by MRFF to a biotechnology company**
- **Bolsters Company's cash position by providing significant non-dilutive funding in addition to successful $23M capital raise (Dec 2020) and an upcoming R&D Rebate**
- **Funding relates to the Company's aim of establishing Veyonda® as a standard enhancer of chemotherapy in cancer patients, a major unmet need in a market valued at >US$50 billion**
- **The funds are for the CEP-2 study, due to start shortly, testing the combination of Veyonda and standard of care chemotherapy drug, doxorubicin, in patients with soft tissue sarcoma.**

Sydney, 15 November 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) proudly announces a major achievement in the form of an A$8.79M Rapid Applied Research Translation Grant from the Australian Government's Medical Research Future Fund (MRFF).

The 3-year grant will fund the CEP-2 study looking at the combination of Veyonda® and standard of care chemotherapy drug, doxorubicin, for the treatment of soft tissue sarcomas (STSs). The grant is intended to meet the cost of the trial, thereby releasing $8.8M for other projects.

This is one of the largest grants by MRFF for any biotechnology company for a single drug program.

Noxopharm continually pursues non-dilutive funding to deliver shareholder value. The scale of this grant is testament to those efforts by Company management led by CMO, Dr Gisela Mautner and COO, Dr Jeanette Bell. It also is an external peer-reviewed validation of the Company's science, with the full grant application being awarded.

The CEP (Chemotherapy Enhancement Program) program builds on extensive pre-clinical studies showing that the active component of Veyonda, idronoxil, is a potent enhancer of the most common chemotherapy drugs, including doxorubicin.[1-3]

As previously announced (*ASX: 7 May 2021, 21 Feb 2020*), the CEP-2 trial was approved by the U.S. FDA under the Investigational New Drug process based upon clinical evidence from the CEP-1 trial that combined Veyonda with the chemotherapy drug, carboplatin, and on preclinical evidence showing that Veyonda boosted the cancer-killing effect of doxorubicin against human sarcoma cells.

Soft tissue sarcomas (STSs) are often fatal cancers, with up to 50% of high-grade STS patients developing metastases and dying within 12 months of diagnosis.

The CEP-2 study is a Phase 1, open label, dose-escalation and dose-expansion study with the Veyonda/doxorubicin combination being given as a first-line treatment. Approximately 45 STS patients will be treated with Veyonda and doxorubicin for up to 6 cycles. Patients will be followed up for up to 18 months for a range of end-points including preliminary efficacy and quality of life end-points.

Noxopharm CEO, Dr Graham Kelly, said, "*This grant not only provides substantial non-dilutive funding to Noxopharm, but it also lends external validation to our work. It also is testament to the extraordinary efforts and talents of our scientific and clinical teams. The MRFF awards a limited number of grants, funding only those projects that are highly rated against a series of strict criteria that are perceived to be capable of turning research findings into real health benefits.*

It is gratifying that this panel of experts saw the potential therapeutic benefit that the CEP-2 study has to cancer patients in Australia, and worldwide, and the potential financial benefit the opportunity has to Australian industry.

It needs to be stressed that the Veyonda/doxorubicin/sarcoma combination is not something we see being limited to this one combination. We view the CEP-2 combination as providing proof-of-concept, potentially opening the way for Veyonda to be used more broadly in combination with many other chemotherapeutics in a wide range of cancers. With chemotherapy remaining the workhorse of cancer treatment, anything that boosts its effectiveness without sacrificing safety will be a major advancement in the fight against cancer.

Fittingly, in this fight, we have dedicated this trial to Jennie Young, a lady who bravely fought sarcoma and, in the process, helped us better understand the potential benefit of Veyonda."

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

DETAILS

The Chemo-Enhancing Opportunity

The 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 is a key plank in that strategy with chemotherapy remaining the backbone of cancer therapy, a position considered likely to continue for the foreseeable future with the global chemotherapy market estimated at in excess of USD$50 billion.

Based on its mechanisms of action, Noxopharm is confident that most chemotherapy drugs in use today would benefit from being combined with Veyonda, thereby creating a multi-billion-dollar drug opportunity. 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 relating to the use of idronoxil (Veyonda active component) in combination with certain chemotherapy drugs and cancer types and that patent has been granted in Europe, Japan and Australia (*ASX: 25 October 2021*), with other territories.

Sarcoma
Noxopharm has selected soft tissue sarcomas as its proof-of-principle indication for demonstrating chemotherapy enhancement by Veyonda

- in part, because sarcoma is a **rare cancer** (estimated 13,400 new cases to be diagnosed in the U.S. in 2021) and marketing approval for rare cancers offers important commercial incentives including potential **Orphan Drug Designation** carrying valuable funding benefits/regulatory review benefits/7-year market exclusivity;
- in part because there is little apparent competition; and
- in part because many sarcomas respond poorly to chemotherapy, including the standard of care, doxorubicin, and the Company has compelling pre-clinical data showing strong enhancement of doxorubicin by idronoxil.

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 45 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 is underway in 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 Medical Research Future Fund (MRFF)
The MRFF is a A$20 billion investment fund supporting health and medical research and innovation to improve the health and wellbeing of Australians.

The Rapid Applied Research Translation Initiative forms part of the MRFF and is investing in research projects that turn research findings into real health benefits that help patients, by bringing together expert groups in health and medical research.

References

1. Brown D et al (2008). *Idronoxil. Drugs of the Future* 2008, 33(10): 844-860 doi: 10.1358/dof.2008.033.10.1260120
2. Silasi D et al (2009). *Phenoxodiol: pharmacology and clinical experience in cancer monotherapy and in combination with chemotherapeutic drugs*. Expert Op Pharmacother 10:6. doi: 10.1517/1465656090283798
3. Alvero A et al (2008). *Phenoxodiol – a chemosensitizer in the midst of cancer chemoresistance*. US Oncology.4:39-41.doi:https://doi: 10.17925/OHR.2008.04.1.39

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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 cytokine release syndrome (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 immunomodulatory functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiation therapies and immune checkpoint inhibitors. Activity against the latter target provides an anti-inflammatory effect, as well as contributing to an anti-cancer action, but also potentially blocking septic shock.

Noxopharm is running comprehensive drug discovery programs in both oncology and inflammation, and is the major shareholder of US biotechnology company, Nyrada Inc (ASX:NYR), active in the areas of drug development for cardiovascular and neurological diseases.

To learn more, please visit: noxopharm.com

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Forward Looking Statements

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