



Noxopharm Limited ([ASX:NOX](#)) | ASX Announcement | 30 April 2021

High Calibre Scientific Journal Reports Success of Veyonda® as Booster of Chemotherapy in Late-Stage Cancer Patients

- CEP-1 Phase 1a/1b trial findings published in quality peer-reviewed journal *Current Therapeutic Research*
- (CEP) Chemo-Enhancing Program is one of the Company's **4-pillars Veyonda® clinical program** designed to establish Veyonda as a blockbuster drug
- Aim of CEP is to show that Veyonda boosts the effectiveness of conventional chemotherapy to allow use of lower, safer dosages of chemotherapy
- CEP-1 delivers proof-of-concept with Veyonda + low dosages of carboplatin resulting in positive anti-cancer outcomes in patients with advanced breast, ovarian, lung and prostate cancer
- Further validation of the science and commercial opportunities of Veyonda.

Sydney 30 April 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to announce that the results from its CEP-1 study (Chemotherapy Enhancement Program) have been published in the peer-reviewed journal *Current Therapeutic Research*.

Positive trial outcome

The Company previously (*ASX Announcement, 29 Nov 2018*) has reported that European researchers found that Veyonda given in combination with low doses of the widely used chemotherapy drug, carboplatin, resulted in a positive outcome in a high proportion of patients, and was safe to use. The publication reported on today presents the complete data after being peer-reviewed.

The patients selected for this trial had late-stage metastatic solid cancers (breast, ovarian, lung, prostate) that had failed previous treatments and were progressive and were considered unlikely to respond to further chemotherapy.

The study demonstrated that the majority of patients had stabilised their disease throughout the treatment course and by the final treatment cycle, 83% of patients treated with 800 mg Veyonda had stable disease or a partial response. The one patient with a partial response had an almost 100% reduction in tumour size at the end of the study.

Noxopharm Chief Medical Officer, Dr Gisela Mautner, said today. ‘Publication in a peer-reviewed journal means that this paper was rigorously evaluated by independent scientists before being accepted for publication. It is heartening to receive this further validation of the science behind Veyonda’.

The publication is available on the following link:

<https://doi.org/10.1016/j.curtheres.2021.100631>

Interpretation of data

The Noxopharm **4-pillars Veyonda strategy** is aimed at proving the ability of Veyonda to enhance the anti-cancer effectiveness of:

1. Externally delivered radiation (DARRT)
2. Internally delivered radiation (LuPIN)
3. Checkpoint inhibitors (IONIC)
4. Chemotherapy (CEP)

The CEP-1 trial involves using Veyonda in combination with low dosages of the standard chemotherapy drug, carboplatin:

- using dosages of carboplatin approximately 25-50% lower than those considered standard
- in patients whose cancers had been heavily pre-treated and were considered unlikely to respond to even standard, higher dosages of chemotherapy
- and to show that the combination treatment was well tolerated.

Pre-clinical work by Noxopharm has shown that idronoxil, the active ingredient in Veyonda, makes cancer cells more susceptible to being killed by chemotherapy by modifying sphingolipid signalling.¹ This action renders cancer cells highly sensitive to most standard chemotherapy drugs, including being able to achieve high rates of kill with very low dosages of chemotherapies.^{2,3} The CEP-1 trial now provides important translational evidence of being able to achieve this effect in the clinic. Importantly, it was achieved using dosages of carboplatin considerably lower than standard use.⁴ Carboplatin is a commonly-used chemotherapy drug with many known serious side-effects when used at standard dosages.⁴

The highest dose of Veyonda used in the CEP-1 study was 800 mg per dose. Since that time, additional clinical studies have shown higher doses of Veyonda up to 1800 mg have been well tolerated. This paves the way for future studies to encompass an even higher dose with potentially added efficacy benefits.

Comment

Noxopharm CEO, Dr Graham Kelly, said, ‘Our 4-pillars Veyonda strategy is behind an ambitious goal of bringing Veyonda to market as a general-purpose drug that boosts the effectiveness of common cancer therapies. One of those pillars, the CEP program, is looking at using Veyonda to make standard chemotherapy more effective in general, but to do it in a way that also makes it a lot safer. If we can achieve that, more patients should benefit with better responses and fewer side-effects. Potentially it also expands the number of patients willing to undergo chemotherapy. The trial data published today puts us well on the road to achieving this goal.

In the laboratory, idronoxil has proven able to render cancer cells hundreds of times more sensitive to standard chemotherapy drugs.^{2,3} The aim of CEP is to use that dramatic sensitising ability to drop the

dosage of chemotherapies to safer levels, while at the same time boosting their anti-cancer effect. In CEP-1, we used carboplatin dosages lower than those normally used. Those dosages would not be expected to have any meaningful anti-cancer effect on their own. However, carboplatin looks to have worked here in cancers that had stopped responding to chemotherapy.

Chemotherapy remains the predominant form of cancer drug therapy for most forms of cancer, making the use of Veyonda a highly attractive proposition for boosting both the effectiveness and safety of this major form of cancer management.'

Next steps

Noxopharm is in the process of reviewing its clinical programs portfolio in respect to a further study in combination with chemotherapy and a market update will be provided in the near future.

References

1. De Luca T et al. NAD⁺/NADH and/or CoQ/CoQH₂ ratios from plasma membrane electron transport may determine ceramide and sphingosine-1-phosphate levels accompanying G1 arrest and apoptosis. *BioFactors*. 2005;25(1-4):43-60.
2. Brown D, Heaton A, Husband A. Idronoxil. *Drugs Fut*. 2008;33(10):844-860.
3. Alvero AB et al. Phenoxodiol – a chemosensitizer in the midst of cancer chemoresistance. *US Oncology*. 2008;4:39-41.
4. Cheng Y. Carboplatin-induced hematotoxicity among patients with non-small cell lung cancer: Analysis on clinical adverse events and drug-gene interactions. *Oncotarget* 2017; 8:32228-32236

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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 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 immunology 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

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.
