



Noxopharm Limited ([ASX:NOX](#)) | ASX Announcement | 4 June 2021

Noxopharm Set to Benefit From Novartis ASCO Data

- Novartis experimental drug, ¹⁷⁷Lutetium-PSMA-617, looks set to become an important new treatment for late-stage prostate cancer on the basis of Phase 3 clinical trial data released overnight
- Noxopharm welcomes this outcome given its recent LuPIN trial data showing even stronger survival outcome when ¹⁷⁷Lutetium-PSMA-617 is combined with Veyonda[®]
- The Novartis VISION study reported a median Overall Survival (mOS) of 15.3 months for ¹⁷⁷Lutetium-PSMA-617 + standard of care versus 11.3 months for standard of care alone
- This compares with 19.7 months for the ¹⁷⁷Lutetium-PSMA-617/Veyonda (LuPIN) combination, an additional 4.4 months over ¹⁷⁷Lutetium-PSMA-617 alone
- Noxopharm now presented with significant opportunity to help grow the market for ¹⁷⁷Lutetium-PSMA-617 and potentially radioligand therapy more broadly
- Data being presented to the Annual Conference of the American Society of Clinical Oncology (ASCO), the foremost cancer conference in the world.

Sydney 4 June 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to acknowledge the release of clinical data relating to the experimental radioligand, [¹⁷⁷Lu]Lutetium-PSMA-617 (Lu-PSMA-617). Headline data from the Phase 3 VISION trial was released overnight, with full details to be presented Monday morning (AEST) to the Annual Meeting of the American Society of Clinical Oncology (ASCO). The VISION trial looked at the effectiveness of Lu-PSMA-617 as a treatment for late-stage prostate cancer. Lu-PSMA-617 is owned by Novartis.

Dr Graham Kelly, Noxopharm CEO and Managing Director, said, *“This result is positive news for Noxopharm for two reasons.*

The first is that it confirms that Veyonda in combination with Lu-PSMA-617 provides a considerable survival advantage over Lu-PSMA-617 alone. The LuPIN mOS outcome of 19.7

months still remains the best survival outcome of any drug approved for use in men with end-stage prostate cancer including enzalutamide, abiraterone, docetaxel, cabazitaxel, and now Lu-PSMA-617.

The second is that having Lu-PSMA-617 likely to come to market as a 3rd line therapy provides a clear development pathway now for Veyonda to come to market itself, with a distinct opportunity to make the Veyonda/Lu-PSMA-617 combination a new standard of care for end-stage prostate cancer.”

The VISION study compared Lu-PSMA-617 with standard of care in men with metastatic castrate-resistant prostate cancer (mCRPC) who had received at least two previous lines of therapy. The trial met its primary endpoint of a median Overall Survival of **15.3 months** versus **11.3 months** for standard of care alone.

This compares with the LuPIN trial that tested the combination of Lu-PSMA-617 and Veyonda in men with end-stage mCRPC who had progressed on at least three previous lines of therapy. The interim median Overall Survival from the LuPIN study currently stands at **19.7 months**.

Due to the strong overall survival benefit in the VISION trial of 4 months (15.3 vs 11.3), Noxopharm believes that it will see Lu-PSMA-617 receive marketing approval in major territories such as the U.S. and EC. with likely introduction to the market in early-2022.

Dr Gisela Mautner, Noxopharm Chief Medical Officer, said, *“Noxopharm welcomes this news because it has a major interest in seeing Lu-PSMA-617 come to market and become a standard of care for prostate cancer.*

The Company believes that the LuPIN study has demonstrated that Veyonda has the ability to enhance the efficacy of Lu-PSMA-617, with a greater survival benefit from the combination than Lu-PSMA-617 alone. This well-tolerated combination therapy should increase the attractiveness of radioligand therapy for men with late-stage prostate cancer even more.”

About Radioligand therapy

A radioligand comprises a compound (ligand) that searches out and attaches to a cancer target, combined with a radioisotope that emits radiation to kill the cancer cell. Radioligand therapy is emerging as a major new form of cancer therapy, offering the ability to deliver radiation, usually intravenously, in a highly targeted manner. Current use largely is limited to the treatment of neuroendocrine tumours and late-stage prostate cancer.

¹⁷⁷Lutetium-PSMA-617 involves an antibody fragment attached to the isotope Lutetium-177. The antibody fragment (peptide) identifies prostate-specific membrane antigen, a surface protein highly expressed by prostate cancer cells. Swiss pharmaceutical company, Novartis, acquired ¹⁷⁷Lutetium-PSMA-617 as part of a series of US\$6 billion transactions in 2018.

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 oncolytic and immunostimulatory functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiotherapy, radioligand therapy and immune checkpoint inhibitor therapy. 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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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.

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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.