**ASX Announcement | 12 October 2020**
**Noxopharm Limited (ASX:NOX)**

# LuPIN Study Achieves Final Patient Treatment

**Highlights:**

- **56-person, dose-response Phase 1b/2a LuPIN study concludes treatment stage**
- **$^{177}$LuPSMA-617 the subject of US$6 billion acquisitions on the basis of a promising new treatment for a proportion of men with late-stage prostate cancer**
- **LuPIN aiming to use immuno-oncology actions of Veyonda® to increase response rates to $^{177}$LuPSMA-617**

**Sydney 12 October 2020: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX)** is pleased to announce that the final patient has completed treatment in the LuPIN study. LuPIN is examining the combination of Veyonda® and $^{177}$LuPSMA-617 in 56 late-stage prostate cancer patients at St Vincent's Hospital, Sydney.

LuPIN is a dose-response study involving 400, 800 and 1200 mg Veyonda® dosages with a constant $^{177}$LuPSMA-617 dosage. Interim data on the first 32 patients (400 and 800 mg dosages) has been presented at major medical conferences and published in a peer-reviewed journal (*see announcements 12 Nov 2019 and 14 Feb, 3 March, 1 Jun and 11 Aug 2020*). These two lower dosages have produced highly encouraging data with impressive tumour response outcomes, most notably a median overall survival of 17.1 months in men with limited survival expectations.

Data from the final 24 patients who received the highest (1200 mg) dosage is yet to be reported, with the last patient just completing his study treatment. The next set of interim data is planned to be presented and published in Q1 2021.

**Potential meaning to NOX shareholders**

$^{177}$LuPSMA-617 therapy, currently an experimental therapy, is anticipated to come to market next year as an approved therapy for late-stage prostate cancer. The Company anticipates that positive dose-response data from the LuPIN study should position Veyonda® to be considered as a combination therapy to improve both the proportion of men responding meaningfully to $^{177}$Lu-PSMA-617 along with the duration of the anti-cancer response.

The Company's primary goal remains to see Veyonda® come to market as a standard immuno-oncology (I-O) drug meeting a current substantial unmet need across a wide range of cancer types. The ability of Veyonda® to repopulate solid tumours with activated immune cells (termed COLD to HOT tumour conversion) marks Veyonda® as a potentially highly valuable second generation I-O drug. The Company's priorities are exploiting that unique action in combination with external beam radiotherapy in prostate

cancer (DARRT program), with $^{177}$LuPSMA-617 therapy in prostate cancer (LuPIN program) and in an as yet to be detailed study combined with a checkpoint inhibitor in a wide range of solid cancer types (IONIC program).

Prostate cancer to date has proven poorly responsive to I-O therapies. The Company sees its DARRT and LuPIN therapies as overcoming that unresponsiveness and bringing a new generation of therapies to this growing age-related problem.

**LuPIN study explained**

The LuPIN (**Lu**tetium-**P**SMA In Combination with **N**OX66) study is an investigator-initiated Phase 1b/2a clinical trial evaluating combination treatment of Veyonda® and $^{177}$Lu-PSMA-617 in late-stage prostate cancer.

$^{177}$Lu-PSMA-617 is an experimental therapy acquired by Novartis in a US$6 billion series of transactions in 2018 and is emerging as a promising last-line or near last-line therapy for prostate cancer that has progressed on standard therapies. The aim of the LuPIN study is to see if adding Veyonda® will lead to a high proportion of men responding to $^{177}$Lu-PSMA-617 as well as leading to a highly durable response.

End-points that have been the subject of interim reports to date include safety, PSA response rate (>50% fall in PSA levels), proportion of men able to complete a full 6-cycle course of treatment, and mean overall survival at 12 months post-treatment.

LuPIN patients have late-stage metastatic castration-resistant prostate cancer which has stopped responding to all standard therapies and who have limited survival prospects. The LuPIN study is distinguished from many others looking at $^{177}$Lu-PSMA-617 therapy in being particularly stringent in only selecting patients who have exhausted all standard treatment options, whereas other studies often use patients with remaining treatment options and therefore are likely to respond better to any treatment. The Company views any response in the LuPIN patients, therefore, as a signal of clinical benefit from the combination treatment.

Noxopharm has been pleased to partner with St Vincent's Hospital Sydney on what has been a low-cost investigator initiated trial for the Company.

*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.*

**-ENDS-**

**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 – inhibition of sphingosine kinase 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 the development of 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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