ASX Announcement |11 August 2020
Noxopharm Limited ASX:NOX

Independent publication in international journal strengthens case for Veyonda® as a safe and possibly life-prolonging treatment in late-stage prostate cancer

Investment Highlights

- Peer-reviewed publication of key LuPIN (Phase 2) study data in international journal of combination ^{177}LuPSMA-617 and Veyonda® in late-stage prostate cancer
- Promising increase in Overall Survival with median 17.1 months. Triple increase compared to only 4.5 months in men who have exhausted all standard treatment options
- Authors conclude that combination treatment of ^{177}LuPSMA-617 and Veyonda® is a safe treatment for late-stage prostate cancer patients

Sydney, 11 August 2020**: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX)** is pleased to announce the publication of the first manuscript of the LuPIN trial in the journal, European Urology Oncology. This journal is the first official publication of the European Association of Urology that is fully devoted to the study of genitourinary cancer. The publication has been peer-reviewed by a panel of experts in the field.

The authors are renowned medical experts from the Kinghorn Cancer Centre, St Vincent's Hospital Sydney, Garvan Institute of Medical Research, Monash University, Sir Peter MacCallum Dept of Oncology, and Princess Margaret Cancer Center, Toronto.

NOX has announced previously interim information about the LuPIN trial on 14th February 2020. The peer-reviewed publication released today describes the details of the LuPIN study, its background, design, treatment interventions and the outcomes for the first 32 patients in this 56-patient study.

The potential of Veyonda®

The authors concluded that in late-stage prostate cancer patients who have exhausted all standard treatment options, a combination of ^{177}LuPSMA-617 and Veyonda® is both safe and delivered promising efficacy outcomes, among them a median Overall Survival of 17.1 months. The authors noted that the median Overall Survival in a study conducted in a comparable patient population (exhausted all standard treatment options; progressive disease) receiving standard chemotherapy was only 4.5 months.

Noxopharm Executive Chairman and CEO Graham Kelly said: "This is excellent news for Noxopharm and adds to the growing evidence that Veyonda® has the means to become a standard of care drug in late-stage prostate cancer. Lu-PSMA-617 therapy is attracting considerable international attention as a promising therapy for men with Stage 4 prostate cancer. It was the subject of a US$6 billion series of acquisitions by Novartis in 2018 and we anticipate it becoming a commercially available drug in 2021.

We see this publication making a solid case for a combination of Veyonda® and Lu-PSMA-617 becoming a standard treatment option in late-stage prostate cancer, particularly given that the combination was well-tolerated, even in patients with advanced disease and very limited survival prospects."

What is the LuPIN study?

The LuPIN study is an investigator-initiated Phase 1b/2a clinical trial evaluating the Company's lead product candidate, Veyonda® in combination with ^{177}Lu-PSMA-617, an experimental radiopharmaceutical therapy owned by Novartis, in patients with late-stage metastatic castration-resistant prostate cancer (mCRPC) who have 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.

Please refer to the link for the full article: https://euoncology.europeanurology.com/inpress

About LuPIN

LuPIN is an Investigator-Initiated Phase Ib/2a, single-arm, open label study enrolling 56 men with mCRPC that had been heavily pre-treated with docetaxel, cabazitaxel and either abiraterone and/or enzalutamide, but whose disease nevertheless was progressing. The study is divided into 4 cohorts of 400 mg (8 patients), 800 mg (8 patients), 800 mg (16 patients) and 1200 mg (24 patients) Veyonda® in combination with ^{177}Lu-PSMA-617.

The Phase 1 part of the study is intended to establish the safety of the combination treatment. The Phase 2 expansion part is intended to establish the dose-response effect of increasing Veyonda® levels in combination treatment.

Imaging inclusion criteria include a PSMA PET/CT with uptake intensity in metastases more than twice the normal liver uptake and no discordant disease on FDG PET/CT. All men receive up to 6 doses of ^{177} Lu-PSMA-617 at 6-weekly intervals and Veyonda® every cycle on days 1-10.

About Noxopharm

Noxopharm Limited (ASX:NOX) is an Australian clinical-stage drug development company focused on treating cancer with Veyonda®, its lead drug candidate.

Veyonda® is a dual-acting oncotoxic and immuno-oncology drug designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapy, radiotherapy and immuno-oncology drugs. The drug acts by harnessing the body's immune system to inflict damage on cancer cells in the body and has shown promise in treating a broad spectrum of cancers.

Veyonda® also is to undergo evaluation as a treatment for septic shock, starting with a Phase 1 study in patients with moderate COVID-19 disease.

Noxopharm also has an active research and development (R&D) program for additional drug candidates and is the major shareholder of US biotechnology company Nyrada Inc. (ASX:NYR).

To learn more please visit: https://www.noxopharm.com/

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Graham Kelly, CEO and Executive Chairman of Noxopharm, has approved the release of this document to the market on behalf of the Board of Directors.

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 that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement.