ASX Announcement | 9 February 2021
Noxopharm Limited (ASX:NOX)

9 February 2021 **Sydney, Australia**

Global Conference to Hear of Major Survival Benefit in Prostate Cancer Patients

- **Noxopharm claims emergence of a major new treatment for prostate cancer**
- **LuPIN drug combination of Veyonda® and ^{177}Lu-PSMA-617 (Novartis) results in half of all patients surviving at least 19.7 months, a ground-breaking outcome for men with end-stage (Stage 4) disease and no remaining treatment options**
- **Data being presented to global cancer conference (11-13 February 2021)**
- **Noxopharm undertaking strategic discussions with respect to making LuPIN treatment a new standard of care**
- **Survival benefit exceeds that reported for any current standard of care treatment including one acquired by Pfizer in 2016 for US$14 billion**

Sydney 9 February 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to report the publication in abstract form of the latest survival data from the LuPIN study ahead of a formal presentation to the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium (11-13 Feb 2021), the pre-eminent medical conference dedicated to sharing the most recent innovations in the treatment of genitourinary cancers.

Noxopharm **CEO, Dr Graham Kelly,** said, "This data has been generated in an independent study and is being shared on the world stage by leading Australian researchers. The reported median overall survival outcome of **19.7 months** means that at least half of men who have progressive end-stage prostate cancer, and who have come to the end of their treatment journey, are being offered at least another 20 months of life. This is an extraordinary outcome and easily exceeds that obtained with any of the current treatments for Stage 4 prostate cancer in their registration studies. That difference is even more remarkable when you consider that those other treatments were tested in men with considerably less advanced disease than those in the LuPIN study."

"Today's clinical data continues to cement the view that Veyonda® (NOX66) is on track to become a major new immunotherapy oncology drug of medical and commercial significance. The DARRT program has already suggested this and the LuPIN program now confirms it. All of which augurs well for our upcoming IONIC program. Collectively, these three programs highlight the diversity of use and potential value of Veyonda," Kelly added.

Conference Data

A team of eminent medical researchers from Sydney's St Vincent's Hospital and Melbourne's Peter MacCallum Cancer Centre and led by Professor Louise Emmett conducted the independent Phase I/II study. They reported that Veyonda was safe and efficacious in combination with ^{177}Lu-PSMA-617, an experimental radiopharmaceutical acquired by major Swiss pharma company, Novartis, three years ago for US$6 billion across a series of transactions.

The LuPIN study enrolled a total of 56 patients with metastatic castration-resistant prostate cancer (mCRPC) whose cancer had progressed on all three standard lines of therapy for late-stage disease. These men were regarded as having reached the end of their treatment journey. The goal of the combined (LuPIN) treatment was to slow or to block tumour progression in order to deliver a better quality of life and extended survival and to do so in a well-tolerated way.

The median Overall Survival (mOS) for the 56 men in the LuPIN study was **19.7 months**, an increase on the **17.1 months** reported 12 months ago (ASX announcement: 14 February 2020) at the same conference for the first 32 men in the study.

mOS is a standard measure of efficacy in cancer studies and is the time at which half the patients remain alive and half are deceased.

- In terms of how much of a survival benefit the LuPIN drug combination has offered, **19.7 months** compares with **4.5 months** reported in a study by Buonerba[1] in men with Stage 4 mCRPC whose disease had progressed on standard therapies

- In terms of how much Veyonda is contributing to the combined drug effect, **19.7 months** compares to **13.3 months** reported in an Australian study[2] where ^{177}Lu-PSMA-617 was used on its own. Overall, the men in that other study had less advanced disease than the men in the LuPIN study, emphasising even more the benefit of the combination versus the Novartis drug on its own.

The data also showed that:

a) **86% of men** had a reduction in blood PSA (prostate specific antigen) levels, indicating a very high rate of response of the cancer to the treatment
b) **53% of men** suffering moderate to strong pain associated with cancer reported a significant reduction in pain. Pain is a particular feature of mCRPC due to secondary prostate tumours spreading predominantly to the skeleton.
c) **46%** of men were able to complete the full 6 cycles of treatment without cancer progression.

Comment

The LuPIN data reinforces the Company's belief that a combination of Veyonda and ^{177}lutetium-PSMA-617 represents the long-awaited forward leap in the treatment of mCRPC, offering a patient with end-stage disease that has progressed on all standard treatments, a high chance of his cancer continuing to respond to treatment and with a potential survival outcome justifying the additional treatment (Figure 1).

The investigators deliberately chose to test the LuPIN combination in men with truly end-stage disease as being the most stringent test possible. The median Overall Survival of **19.7 months** shows that the drug combination passed this test beyond the Company's expectations. Providing men at this stage of their disease with an opportunity to achieve an average of about 20 months of life, and obviously longer in some men, is a considerable achievement.

Compared to the Buonerba study, the LuPIN two-drug combination has added over **15 months of additional survival** to men with end-stage cancer, a clinically significant benefit that the Company believes will revolutionise the treatment of late-stage mCRPC.

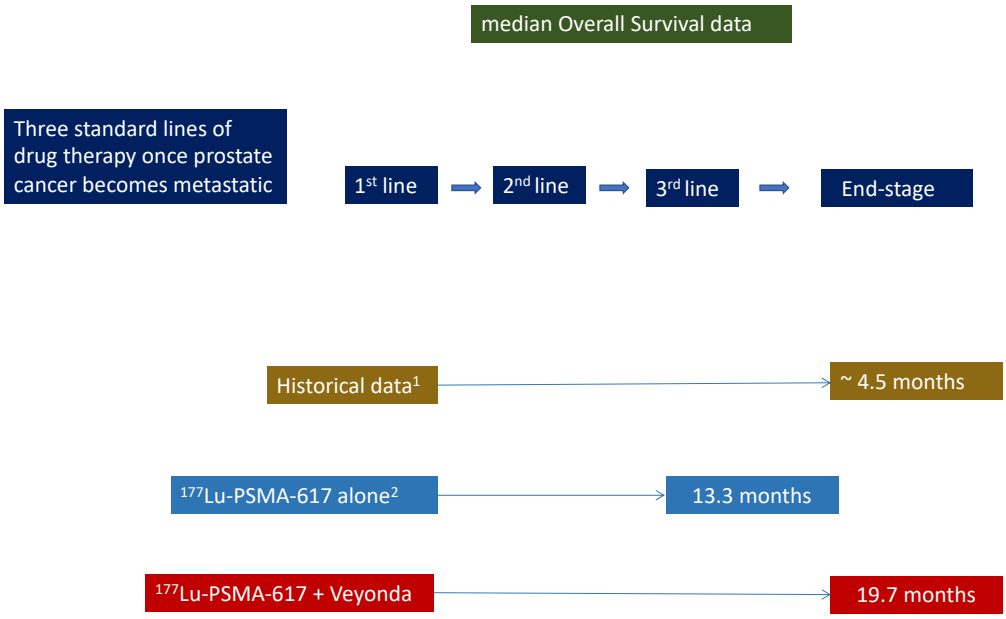

Figure 1. Survival outcomes for men with mCRPC; comparison of 3 studies

Next Steps

While the LuPIN data justifies a strategy of bringing the LuPIN drug combination to market as a new final treatment, moving the treatment to earlier in the disease process is an obvious next step as (i) the cancers generally would be more sensitive to treatment and therefore likely to result in an even greater survival

benefit, and (ii) the high attrition rate in Stage 4 prostate cancer means that there are far more patients requiring earlier treatment than later treatment.

The standard treatment for mCRPC involves three separate courses of therapy designated 1st, 2nd and 3rd line treatment. This comprises two lines of chemotherapy (docetaxel and cabazitaxel) and one line of hormone therapy (enzalutamide or abiraterone), all used in various sequences.

All four current therapies were approved for use on the basis of offering mOS outcomes in the range of **14.8 – 18.4 months**. **Not only has the LuPIN outcome exceeded these outcomes, but it has done so in men whose cancer has progressed on all those therapies.**

The Company notes that one of those therapies, enzalutamide, was the subject of a US$14 billion acquisition by Pfizer in 2016, approved for marketing in 2012 on the basis of a 5-month increase in mOS from 13.6 to 18.4 months. Again, it is worth noting that the LuPIN outcome of 19.7 months has been achieved in men whose cancer has already progressed on enzalutamide.

As part of its next step, Noxopharm has assembled a business development team comprising legal and ex-major pharmaceutical industry executives to advise on appropriate clinical, commercial and transactional strategies in light of the Company's multiple opportunities.

Other

The abstract was published today on the conference website (8 Feb 2021 at 5pm USA ET) and a link is in the process of being put on the Noxopharm website. A link also will be provided in due course to the full poster presentation during the conference on 11-13 Feb 2021.

References:

1. https://www.futuremedicine.com/doi/10.2217/fon.14.71
2. https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.7_suppl.228

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 LuPIN

LuPIN is an Investigator-Initiated Phase Ib/2a, single-arm, open label study which enrolled 56 men with mCRPC who were PSMA-positive and who had been heavily pre-treated with docetaxel, cabazitaxel and either abiraterone and/or enzalutamide, but whose disease nevertheless was progressing. The study was divided into 4 cohorts of 400 mg (8 patients), 800 mg (8 patients), 800 mg (16 patients) and 1200 mg (24 patients) Veyonda (NOX66) in combination with ^{177}Lu-PSMA-617.

The Phase 1 part of the study was intended to establish the safety of the combination treatment. The Phase 2 expansion part was intended to determine preliminary efficacy signals of Veyonda 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 received 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 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 trialing. Veyonda has three main drug actions – highly selective inhibition of sphingosine kinase, STING signaling and autophagy. Sphingosine kinase inhibition contributes to its dual-acting oncotoxic and immuno-oncology functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies and immune checkpoint inhibitors; STING signaling inhibition provides an anti-inflammatory effect, contributing to an anti-cancer action, but also potentially blocking sepsis; autophagy inhibition is believed to augment the immunotherapy effect of radiotherapy, in particular the triggering of an abscopal response.

Noxopharm also is the major shareholder of US biotechnology company Nyrada Inc (ASX:NYR), and wholly owns Pharmorage, a private drug development company focused on drug development in the areas of sepsis and autoimmunity.

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