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Sydney, Australia

Pronounced survival benefit in LuPIN interim trial data

Highlights

- Interim data from 32 men with end-stage prostate cancer treated with combination Veyonda® and ¹⁷⁷Lu-PSMA-617
- Median Overall Survival was very long (17.1 months), a remarkable outcome for end-stage prostate cancer
- 62.5% of patients had an anti-cancer effect as evidenced by a PSA response and half of the patients experiencing severe pain reported a significant pain reduction
- 47% of patients able to complete full 6 courses of treatment
- Combination treatment was safe and well tolerated
- Final 24 patients now receiving combination with higher Veyonda® dose (1200 mg)

Sydney, 14 February 2020: Noxopharm (ASX: NOX) is pleased to announce positive interim results from its LuPIN phase I/II clinical trial. The data was presented today during a poster presentation at the ASCO Genitourinary Cancers (GU) Symposium 2020, in San Francisco, USA, by St Vincent's Hospital Sydney.

The LuPIN study is being conducted by St Vincent's Hospital Sydney and is evaluating Noxopharm lead product candidate, Veyonda®, in combination with ¹⁷⁷Lu-PSMA-617, a radiopharmaceutical therapy, in 56 patients with late-stage metastatic castration-resistant prostate cancer (mCRPC). The data presented at ASCO GU today reports the interim results from the first 32 patients receiving the combination.

Dr Gisela Mautner, Noxopharm Chief Medical Officer, said:

"Today's results are highly encouraging for patients, for Noxopharm and for the St Vincent's Hospital Sydney team. The study reported an unprecedented median Overall Survival of 17.1 months in a patient group that normally would have a much shorter survival expectation. The combination treatment of Veyonda® and ¹⁷⁷Lu-PSMA-617 has delivered a clinically meaningful and strong anti-cancer effect in a high proportion of men and importantly continues to have an excellent safety profile."



“These interim results are highly relevant for a patient group that is at the very end of their treatment journey with very limited life expectancy. The data boosts our confidence that Veyonda® will prove to be of major benefit for a high proportion of patients with late-stage prostate cancer. The study investigators at St Vincent’s Hospital Sydney continue to do excellent work through the LuPIN trial and we are pleased to support them.”

Patient profiles

All patients had received and failed two prior lines of therapy (chemotherapy and androgen-signalling inhibitors) and most patients (29/32) had failed a third line of therapy (another chemotherapy) prior to entering the trial.

The advanced nature of the disease in the LuPIN patients is highlighted by the following:

- The extensive treatment history of most LuPIN patients means that their disease is more advanced and more resistant to therapy than in other studies where patients have had fewer lines of drug therapy
- The majority of patients (65%) had a significant tumour burden with over 20 secondary tumours mainly in the bones and lymph nodes
- All patients had progressive end-stage prostate cancer.

Key efficacy findings

- Median Overall Survival was 17.1 months, indicating a significantly longer survival duration than clinically expected
- 47% of patients (15/32) were well enough to receive all 6 cycles of therapy, indicating a durable response, enabling them to continue to receive treatment until the end of the study
- 87% of patients (28/32) had a fall in PSA (an important marker for anti-cancer activity) and 62.5% (20/32) had a strong PSA response of over 50%
- Half of the patients with severe pain at study start (12/24) had a significant reduction of their pain due to the secondary tumours, supporting the above efficacy results.

Efficacy summary: The combination treatment had a beneficial impact in more than half of the patients.

Key safety findings

Veyonda® combined with ¹⁷⁷Lu-PSMA-617 continues to have a good safety profile, with approximately half the patients experiencing only mild adverse events, such as dry mouth (17/32), fatigue (15/32) and anaemia (14/32). Minimal higher-grade side effects were reported and all were manageable.



Noxopharm Executive Chairman and CEO, Dr Graham Kelly, said:

“Being able to deliver a meaningful anti-cancer response for at least 50% of patients with Stage 4 of any form of cancer would be a remarkable outcome. It is even more noteworthy to do so in late-stage prostate cancer where the disease typically involves a substantial number of secondary tumours in the skeleton, presenting a large and poorly accessible tumour load. A median Overall Survival of 17.1 months, plus the ability to offer at least a 50% chance of achieving a meaningful response, should be seen as highly positive outcomes.”

“¹⁷⁷Lu-PSMA-617 is an encouraging new treatment option for late-stage prostate cancer, with its potential recognised in 2018 by being the subject of a US\$6 billion series of acquisitions by Novartis. Our belief is that Veyonda® works in a way that will provide a worthwhile boost to all radiopharmaceuticals, not just ¹⁷⁷Lu-PSMA-617.”

Further data

Today’s data is from the first 32 men receiving Veyonda® dosages of 400 mg (8 men) and 800 mg (24 men). Further interim data later this year is expected to report on the final 24 men receiving 1200 mg Veyonda®. The Phase I/II LuPIN Study is expected to provide a final read-out in mid-2021.

About LuPIN

LuPIN is an Investigator-Initiated Phase I/II, single-arm, open label study enrolling 56 men with mCRPC whose disease was progressing despite docetaxel, cabazitaxel and either abiraterone and/or enzalutamide. 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 ¹⁷⁷Lu-PSMA-617.

The Phase I part of the study is intended to establish the safety of the combination treatment. The Phase II 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 ¹⁷⁷Lu-PSMA-617 at 6-weekly intervals and Veyonda® every cycle on days 1-10.

About Veyonda®

Veyonda® is a suppository dosage form of idronoxil, a first-in-class inhibitor of sphingosine-1-phosphate (S1P). S1P is a key secondary messenger in cells, with dual roles of activating major pro-survival signalling pathways and regulating immune cell trafficking in tissues. Many solid cancers over-express S1P, supporting unregulated tumour growth and suppressing immune cell populations and activities in tumours. By inhibiting this over-expression, idronoxil acts as both a radio-sensitiser and chemo-sensitiser, and as an immunotherapy, intended to restore immune function to tumours.

About Noxopharm



Noxopharm is a clinical-stage Australian oncology drug development company with offices in Sydney and New York. The Company has a primary focus on the development of Veyonda® and is the major shareholder in the non-oncology drug development company, Nyrada Inc. (ASX:NYR)

www.noxopharm.com

Investor & Corporate Enquiries:

Prue Kelly
M: 0459 022 445
E: info@noxopharm.com

Company Secretary:

David Franks
T: +61 2 8072 1400
E: David.Franks@automicgroup.com.au

Media queries:

Catherine Strong
Citadel-MAGNUS
T: 02 8234 0111
E: cstrong@citadelmagnus.com

Graham Kelly, CEO and Chairman of Noxopharm, has approved the release of this document to the market.

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.