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NOX Announces Positive Data from CEP-1 Study of Veyonda®

- **Final CEP-1 data confirm tolerability of Veyonda® alone and in combination with carboplatin**
- **Halt in progression of cancer growth in 50% of patients**
- **Study provides proof-of-concept for well-tolerated chemotherapy with meaningful survival benefit**

SYDNEY, November 29, 2018, Noxopharm (ASX: NOX) announces the final results from its Phase 1b CEP-1 trial evaluating its lead immuno-oncology/radio-enhancer drug candidate, Veyonda®, in combination with low-dose carboplatin in late-stage metastatic solid cancers.

The CEP-1 trial was a first-in-human study for Veyonda® and was designed to confirm the safety of Veyonda® both as a monotherapy and in combination with chemotherapy, as well as patient and doctor acceptance of the treatment regimen. The study, which ran between January 2017 and July 2018, was managed by a UK-based clinical research organisation and conducted in the European country of Georgia at sites subject to FDA audit. Top line data was presented earlier at the Clinical Oncology Society of Australia (COSA) Annual Meeting on 13 November 2018. With the Final Report now received, the Company is able to comment on the outcome, in particular, the effect of treatment on cancer progression.

The topline outcomes of the study are:

- Veyonda® was well tolerated as a monotherapy, with just 1 case of anemia attributed to it
- Veyonda® at 400mg and 800 mg dosages did not exacerbate carboplatin toxicity
- A combination of Veyonda® and low-dose carboplatin provided suspension of tumour growth, or better, for at least 6 months in solid tumours (breast, ovarian, lung, prostate) in nearly 50% of patients considered unlikely to respond to further chemotherapy
- The Company believes that the response rate and ongoing survival of patients post-study, suggests that a meaningful increase in survival is achievable and therefore worthy of consideration of an eventual marketing approval process
- The Company also believes that this points to a combination of Veyonda® and low-dose carboplatin as offering a potential treatment option for those cancer patients considered too unwell to undergo chemotherapy and/or unlikely to respond to chemotherapy because of their cancer becoming unresponsive to chemotherapy.

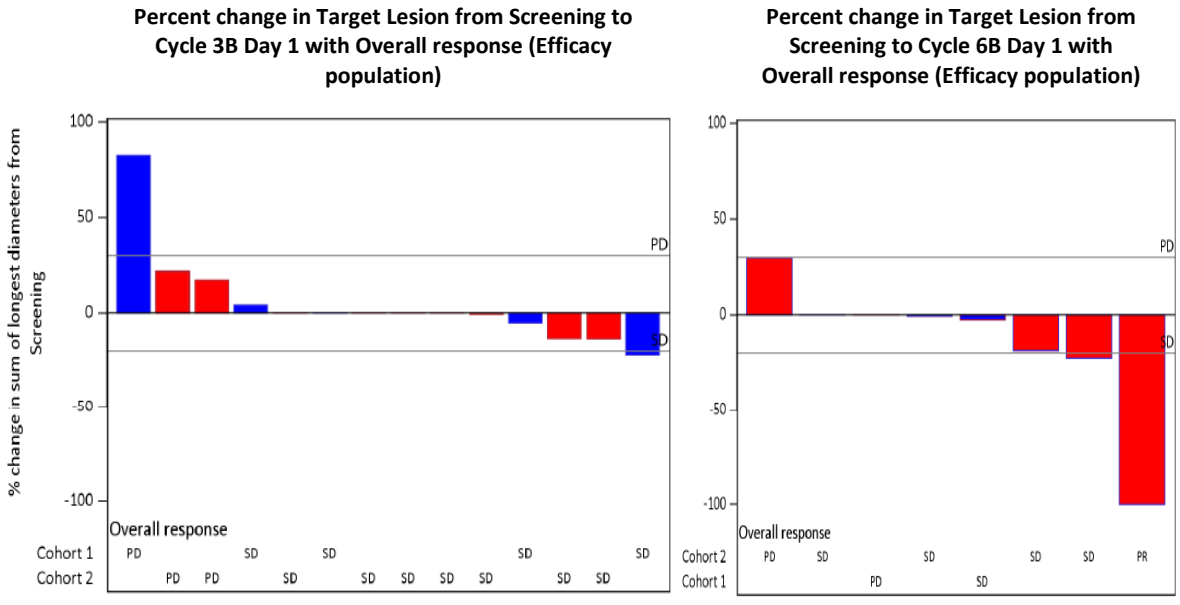
Study details. CEP-1 recruited 19 subjects with late-stage metastatic solid cancers (breast, ovarian, lung, prostate) who had stopped responding to chemotherapy, including carboplatin, and for whom no remaining standard treatment options were available. All patients entered the study with progressive disease and were assessed as having limited survival prospects. Subjects were administered Veyonda® as a monotherapy for the first month and then in combination with two dosages of carboplatin (3 cycles of carboplatin followed by 3 cycles of carboplatin at 50% and 75% respectively of a standard dose) over six months, producing a 7-month treatment course in full.

Safety: With the exception of one (1) patient who displayed hypersensitivity to carboplatin at the initial injection, in no case was toxicity severe enough to require combination therapy needing to be withheld or have the dosage reduced.

Overall, 83% of patients experienced 1 or more adverse events, the majority during combination therapy. The most common events were anaemia (low red blood cells), neutropenia (low white blood cells) and hypocalcemia (low blood calcium levels). 95% of events occurred during combination therapy, of which 80% were attributed to carboplatin. One (1) severe case of anaemia was reported during monotherapy and possibly attributed to Veyonda®.

Cancer status: A high proportion of patients showed tumour responses ranging from stable disease (a halt in disease progression) to partial response (decreased tumour load), despite a patient population that was heavily pre-treated with chemotherapy and assessed as ineligible for further treatment. Individual efficacy results for patients assessable after 3 cycles of combination therapy (left figure) and after 6 cycles (right figure) are detailed in the figure below. Bars reflect the change in total tumor(s) size for each patient and annotations show categorical response according to RECIST 1.1 criteria (PR = partial response; SD = stable disease; PD = progressive disease) for the same patients. Fourteen patients completed 3 cycles and were able to be assessed; 8 completed 6 cycles and were able to be assessed.

At 3-months, 10 of 14 patients had shown no tumour progression; 8 of these were evaluable after a further 3 cycles (6 cycles total) and of these, 6 patients had shown no disease progression at the end of the study, including one partial responder with an almost 100% reduction in tumour size.



Rationale: The active ingredient in Veyonda®, idronoxil, restores sensitivity to carboplatin in cancer cells that have stopped responding to carboplatin after multiple courses of treatment. The rationale of the CEP program is that Veyonda® will restore sensitivity to chemotherapy or will act synergistically with chemotherapy, such that the dosage of chemotherapy can be lowered to a tolerable level, if required. The ultimate objective is to utilize Veyonda® as a chemo-sensitizer to provide meaningful anti-cancer effects while avoiding serious side-effects that are often treatment-limiting, particularly in in patients considered too unwell to undergo cancer therapy. The CEP regimen also offers the prospect of improving tolerability of chemotherapy regimens in children, where successful treatment with chemotherapy can come at the cost of toxicities with long-term sequelae.

Comments: "The CEP-1 data are highly encouraging, suggesting that in addition to serving as a potential enhancer of radiotherapy, Veyonda® appears to have broader utility as an enhancer of chemotherapy as well," said Greg van Wyk M.D., Noxopharm Chief Medical Officer. "Chemotherapy-induced toxicity remains a significant challenge for patients and oncologists that can lead to long-lasting and debilitating side effects, such as peripheral nerve damage and hearing loss. We are hopeful that combining Veyonda® with a lower than normal dosage of chemotherapy will provide a more tolerable treatment option for patients who have chemotherapy-resistant disease or who are only able to tolerate lower doses of chemotherapy."

Graham Kelly Ph.D., Noxopharm Chief Executive Officer, said, "We believe that this result goes a considerable way to confirming the good tolerability and efficacy of Veyonda®. A high incidence of an anti-cancer effect in such a highly treatment-resistant patient population is very pleasing. The context here is that these patients had progressive disease, had exhausted standard treatment options, and were facing a limited lifespan. To be able to stop tumour growth or to even shrink the tumours in many of these patients over the 7 months of this study, and to do so without significant side-effects, substantiates the faith we have in this drug becoming an important addition to standard anti-cancer therapy."

"Noxopharm is committed to bringing Veyonda® to market as a radio-enhancer with a strategy that we believe will see it on-market by 2022, but the CEP-1 outcome adds another dimension to our overall clinical and marketing strategies," Kelly added.

The Company now will consult with its advisors on a Phase 2 CEP study in Australian cancer patients, although its primary focus remains on its DARRT and LuPIN programs as being the likely quickest routes to market.

A family of three patents surrounding Veyonda®, including one pertaining to use with chemotherapy, has entered the global national phase following a review by the International Examiner.

About Veyonda®

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to preserve the anti-cancer activity of idronoxil in the body and to enhance its drug-like behaviour. Idronoxil is a kinase inhibitor that works by inhibiting a range of enzymes, pre-eminent among which is sphingosine kinase, a key regulator of cell pro-survival mechanisms, and which is over-expressed in many cancer cells. Idronoxil also is an immuno-oncology drug, activating the body's innate immune system e.g. natural killer (NK) cells.

About CEP

The Company's CEP Program (Chemotherapy Enhancement Program) is testing the ability of Veyonda® to restore sensitivity of cancer cells to carboplatin in patients whose late-stage cancers have stopped responding to chemotherapy, and to do that to the extent that the dosage of carboplatin can be lowered to a level unlikely to cause serious adverse side-effects. The clinical outcome being sought is the ability to offer a well-tolerated chemotherapy regimen to patients considered unsuitable for standard dosage due to age or illness.

About Noxopharm

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney, Hong Kong and New York. The Company has a primary focus on the development of drugs based on an isoflavonoid chemical structure. Veyonda® is the first pipeline product, with 3 other drug candidates for non-oncology indications under development in a subsidiary company.

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