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Sydney, Australia

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NOX to Present Clinical Data at COSA Annual Meeting

- **Clinical Oncology Society of Australia**
- **Provides updates on CEP-1 and DARRT-1 clinical studies**
- **Confirms tolerability of Veyonda[®]**
- **Evidence of durable halt of tumour progression in both studies**

SYDNEY, November 13, 2018, Noxopharm (ASX: NOX) announces that it is presenting two posters at the 45th Annual Meeting of the Clinical Oncology Society of Australia (COSA) which is being held November 13-15 in Perth, Australia.

Details of the presentations are as follows:

Title: Trial in Progress: NOX66 in Combination with Palliative Radiotherapy in Patients with mCRPC – a Phase 1 Safety and Dose-Finding Study

Authors: Isabell Vocks PhD, Anne Capp MB BS

Date and time: 14th November; 3.20 pm

Location: Poster #343

This first presentation provides an update on the Company's ongoing open-label Phase 1b study evaluating Veyonda[®] in combination with palliative external beam radiotherapy in men with metastatic castrate-resistant prostate cancer (mCRPC) (DARRT-1). The study is in two parts. The first part is a dose-finding study of 400, 800 and 1200 mg of Veyonda[®]; 4 patients in each cohort (Cohorts 1, 2 and 3 respectively). In the second part of the study, a final group of twelve patients (Cohort 4) then will use the dose of Veyonda[®] determined to be the optimum. The first 3 Cohorts have been fully enrolled and have completed their treatment. Cohort 4 is due to begin enrolment in December 2018.

Dr. Greg van Wyk, Noxopharm Chief Medical Officer, explained, "Our last report on this study referred to four patients in Cohort 1, two in Cohort 2, and one in Cohort 3 who had undergone treatment and reached at least the 6-week review point. The COSA data relates purely to the two to three months of additional follow-up on these seven patients."

"Over the last couple of months we have fully enrolled Cohorts 2 and 3 and these patients now have completed their treatment. The next step is a scheduled review of all Cohort 1-3 patients at the end of November 2018 and we look forward to releasing the outcome of that review in December."

The purpose of DARRT-1 is to assess the safety and efficacy of a short course of Veyonda[®] in both boosting the anti-cancer effect of radiation and in stimulating an immune response intended to lead to an abscopal response. Clinical response is being determined by scans using RECIST (Response

Evaluation Criteria in Solid Tumors) criteria that measure the size and number of all measurable tumours in the body, and determine whether the disease has progressed, remained stable, or responded (partially or completely). In patients whose tumours are difficult to measure, clinical response is being determined on the basis of PSA levels and pain scores.

Cohort 1 (400 mg Veyonda[®]): 3 patients (Patients # 1-3) were assessed at 12 weeks as having stable disease by scan (RECIST assessment). At 24 weeks, Patients #1 and 3 remain stable on the basis of scans, while Patient # 2 has progressed.

Cohort 2 (800 mg): 1 patient (#7) was assessed at 12 weeks as having a partial response. At 24 weeks this patient continues to have a partial response including a strong decreasing PSA response.

Cohort 3 (1,200 mg): Patient #9 at 12 weeks continues to have a partial response and a strong decreasing PSA response.

Dr. Kelly, Noxopharm Chief Executive Officer, commented, "Notwithstanding the low patient numbers at this stage, Veyonda[®], when administered at the likely therapeutic doses of 800 mg or 1,200 mg, appears to provide a high rate of response that also appears to be durable. The implication here is that we are seeing a clinical benefit in men who have progressive, late-stage, metastatic disease and who have exhausted all available treatment options. That we have been able to achieve a meaningful anti-cancer effect in these men with only palliative doses of radiotherapy in combination with a short course of Veyonda[®] is highly encouraging."

"To achieve marketing approval, Veyonda[®] is going to need to show an ability to delay tumor progression to a meaningful extent, which for a number of drugs in the past has only needed to be several months. That is why the apparent durability of the responses in this study for 6 months to date, including PSA levels continuing to fall well after treatment has stopped, is so encouraging. We believe the combination of Veyonda[®] and palliative radiotherapy represents a potentially transformative treatment for late-stage prostate cancer and we look forward to the additional data from DARRT-1 in coming weeks."

Title: A Phase 1 Study of NOX66 in Combination with Carboplatin in Patients with End-Stage Solid Tumours

Authors: Marinella Messina PhD, Ian Minns, Paul de Souza MB BS, Mikheil Shavdia MD, Nana Chikhladze MD, Graham Kelly PhD

Date and time: 14th November 2018: 3.20 pm

Location: Poster #427

The second presentation provides a more detailed analysis of the safety and efficacy end-points than previously reported on the Company's open label Phase 1b study, known as CEP-1, evaluating Veyonda[®] in combination with carboplatin.

The CEP (Chemotherapy Enhancement Program) program is evaluating the ability of Veyonda[®] to restore responsiveness to carboplatin in chemo-resistant cancers to the extent that even lower, better tolerated dosages of chemotherapy can be used. This first-in-human trial of Veyonda[®] was an important proof-of-principle study for the Company, confirming the drug's safety and patient acceptance. The study, which concluded in July 2018, was conducted in Georgia, using sites subject to FDA audit.

Dr. van Wyk said, "End-of-trial data typically undergoes comprehensive analysis and review lasting up to 6 months. We anticipate receiving the top line report for the CEP program by the end of November after which it will be released publicly. The COSA data is headline data ahead of that report."

CEP-1 recruited 19 people with late-stage metastatic solid cancers 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. Veyonda[®] was administered as monotherapy for the first month and then in combination with carboplatin (between 50 and 75% of standard dosages) over six months. The key findings were: (i) that no dose-limiting toxicity was observed with the combination therapy, and (ii) 45% of patients had stable disease or better (1 patient with metastatic breast cancer had a partial response) at the end of the seven-month study.

Graham Kelly said, "We originally saw the CEP approach as being a treatment option for the significant number of patients considered for various health reasons to be unsuitable for further chemotherapy. On top of which a significant number of cancer patients also decline further treatment when faced with the prospect of side-effects. The original CEP concept was to offer these patients the opportunity to be able to use chemotherapy without experiencing damaging side-effects. The good tolerance of the Veyonda[®]/carboplatin combination shows that this can be done. And the 45% clinical response rate for late-stage cancers with no standard treatment options is particularly encouraging considering only half of study participants received the higher dosage of Veyonda[®]."

"These data suggest that there may be a role for Veyonda[®] more broadly and not just in patients considered unsuitable for chemotherapy. While the sample size is small, the response rate in the five breast cancer patients in the study is a particularly noteworthy outcome and potentially could inform the future direction of this program," Kelly added.

About COSA

The COSA Annual Scientific Meeting (ASM) is Australia's premier cancer meeting, held over three days each year, usually in November. The ASM is a multidisciplinary meeting, inviting participation from doctors, nurses, allied health professionals and scientists working in cancer care nationally and internationally. A different state hosts the ASM each year, with a specific theme and focus on a specific cancer type.

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 eg. natural killer (NK) cells.

About DARRT

The Company's DARRT (Direct and Abscopal Response to Radiotherapy) Program is testing the ability of Veyonda[®] to increase tumour response to palliative dosages of radiotherapy. The DARRT treatment regimen entails a 5-day course of radiotherapy (20-30 Gy) in 5 fractionated dosages targeting 1-2 larger tumours, and the Veyonda[®] administered daily for up to 3 weeks. The rationale of DARRT is to combine the radio-enhancing properties of Veyonda[®] that stem from its sphingosine kinase inhibition, with its ability to stimulate the body's first line immune defence cells against cancer. The clinical outcome being sought is greater shrinkage of irradiated tumours and shrinkage of all non-irradiated tumours (abscopal response).

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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Forward Looking Statements

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Trial in Progress: NOX66 in combination with Palliative Radiotherapy in patients with CRPC – a Phase 1 safety and dose finding study

Dr Isabell Vocks¹, Dr Anne Capp²
 (¹Noxopharm Limited, ²Genesis CancerCare Newcastle)

Background

The naturally occurring isoflavone, genistein, has been investigated for its potential chemo-protective and anti-cancer activity, with multiple pharmacological properties being identified including direct induction of apoptosis and prevention of cell repair and growth. These findings led to the development of isoflavonoids - molecules based on the chemical structure of genistein - designed to enhance the chemotherapeutic and antineoplastic effects. One of these compounds - idronoxil - has been shown *in vitro* to sensitize multiple cancer cell lines to common chemotherapies, in some cases by up to 2000 fold. Recent *in vitro* studies have shown sensitization of prostate cancer cells to the effects of radiotherapy. Furthermore, evidence suggests that idronoxil may stimulate an increase in NK cell activity - it is theorised that an immunostimulatory effect may support an abscopal response in patients being treated with radiotherapy. A previous Phase 3 study of idronoxil in ovarian cancer, however, failed to show improved efficacy when compared with standard chemotherapy alone. It is believed that this lack of efficacy was due to the rapid metabolism and elimination of idronoxil.

NOX66, a novel formulation of idronoxil as an active ingredient and designed for rectal administration, is under clinical investigation in combination with chemotherapy and radiotherapy. NOX66 is designed to protect idronoxil from rapid metabolism and elimination, allowing for therapeutic levels of idronoxil to remain in the body. A Phase 1 study of NOX66 as monotherapy and in combination with chemotherapy (carboplatin) has been completed, showing NOX66 to be suitably tolerated.

Here we describe the design of, and provide preliminary safety data for, a first-in-human study of NOX66 in combination with radiotherapy in patients with late-stage prostate cancer, investigating the safety of three dose levels of NOX66.

Study Title: NOX66 and Palliative Radiotherapy in Patients with Late-Stage Prostate Cancer - A Phase 1b Proof of Concept and Dose Confirmation Study

ClinicalTrials.gov Identifier: NCT03307629

KEY Inclusion criteria

Histologically confirmed prostate cancer and/or PSA of >100 ng/mL at original diagnosis.

Metastatic disease evidenced by either CT/MRI imaging or bone scan.

Objective evidence of disease progression.

Eligible to receive palliative radiation therapy for management of disease.

One symptomatic lesions suitable for Radiation Therapy.

KEY Exclusion criteria

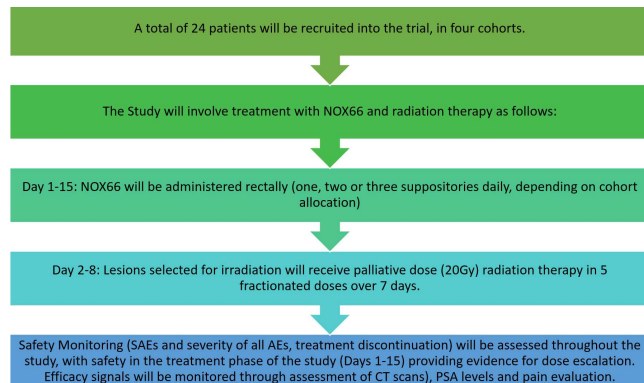
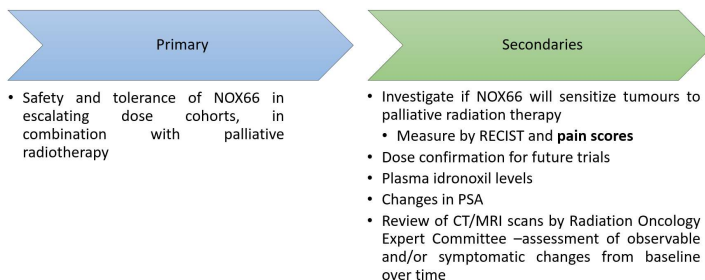
Tumour involvement of the central nervous system.

Concurrent systemic chemotherapy or biological therapy.

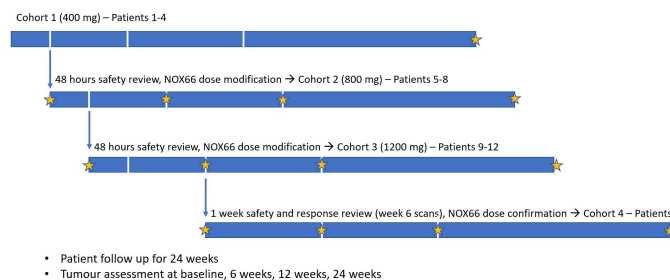
Any situation where the use of suppository therapy is contra-indicated or impractical.

Study Methodology

Objectives



Dose Escalation



Study Progress—Results

Recruitment commenced in March 2018, at eleven centres in Australia (5), New Zealand (1) and Georgia (5).

At the time of writing, 14 of 24 patients have been recruited, Cohort 3 has been completed and 2 replacement patients for Cohort 2 have been included. Results in table 1 show patient data of 9 patients with dataset available to this date.

Patient	Cohort	Efficacy							Safety		
		Baseline PSA	6-week PSA (ng/ml)	12-week PSA (ng/ml)	24-week PSA (ng/ml)	RECIST assessment at 6 weeks	RECIST assessment at 12 weeks	RECIST assessment at 24 weeks	Adverse Events > Grade 2	Related to NOX66	Related to RT
01	1/400 mg	2044	2593	2117	1945	SD	SD	SD	NIL	NA	NA
02	1/400 mg	67.7	87.4	100	624.1	SD	SD	NE	NIL	NA	NA
03	1/400 mg	315	183	370	819	SD	SD	SD	NIL	NA	NA
04	1/400 mg	350	550	610	1600	PD	NE	PD	NIL	NA	NA
05	2/800 mg	440	ND	947	ND	ND	PD	Deceased	Anaemia, Hypophosphatemia, Disease Progression	UR	UR
06	2/800 mg	150	Deceased	ND	ND	ND	ND	ND	Vomiting, Nausea, Decreased lymphocyte count, Hypocalcemia, Death	UR	UR
07	2/800 mg	15.5	6	5.2	2.2	SD	PR	PR	NIL	NA	NA
08	2/800 mg	152	143	ND	ND	ND	Deceased	ND	Death	UR	UR
09	3/1200 mg	80.5	42.5	17.3	TBD	PR	PR	TBD	NIL	NA	NA

Safety: Up to this date at least 5 patients experienced one or more Adverse Events (AE)s. Three of the overall AEs were considered possibly related (PR) to NOX66 and these were mild (Grade 1). All severe AEs were considered unrelated to either NOX66 or RT, and were due to progressive disease, as shown in Table 1.

Preliminary efficacy: Of the 9 evaluable patients receiving one dose of NOX66, Patient 07 in Cohort 2 (800 mg) showed Partial Response in the overall RECIST analysis for week 24. This patient's PSA decreased > 75 % at week 12 and week 24. Patient 09 in Cohort 3 (1200 mg) showed Partial Response in overall RECIST analysis for week 12. The PSA decreased > 75% at week 12.

A phase 1 study of NOX66 in combination with carboplatin in patients with end stage solid tumours

Marinella Messina¹, Ian Minns¹, Paul deSouza², Mikheil Shavdia³, Nana Chikhladze³, Graham Kelly¹

¹Noxopharm Limited, (Gordon, Australia), ²University of Western Sydney (Liverpool, Australia), ³JSC Neo Medi (Tbilisi, Georgia), ⁴Tbilisi State Medical University's First University Clinic (Tbilisi, Georgia)

Background

NOX66 is a novel formulation of the isoflavonoid, idronoxil, in a lipophilic base and is being developed as an enhancer of chemotherapy and radiotherapy. The primary mechanism of action of idronoxil stems from its selective binding to a tumour-specific NADH oxidase, ENOX2, inhibiting Sphingosine kinase activity, leading to inhibition of the PI3K/Akt pathway and induction of apoptosis. While the mode of action of idronoxil suggests a direct cytotoxic effect as a monotherapy, research has focused on using lower doses of idronoxil to enhance the effect of standard therapies. *In vitro* studies of Phenoxodiol (previous nomenclature for idronoxil) with platinum based therapies has shown up to 2000 fold increase in the cytotoxic effects and reversal of pre-existing resistance and reduces the dose necessary to obtain antitumoural effect. In xenograft models of range tissue types, Idronoxil enhances the cytotoxic effects of carboplatin and other antineoplastic⁽¹⁾. Preliminary evidence suggests that idronoxil may also stimulate an immune response via a NK cell pathway⁽²⁾– this may provide a complimentary effect to chemotherapy treatments and support the effects of radiotherapy both at the sites of irradiation and in tumours not irradiated.

NOX66 has been formulated to extend the effective half life of idronoxil with studies in rats indicating that half life of the parent idronoxil is increased to from <60 min when administered orally to >6h when administered rectally as NOX66⁽³⁾. The low bioavailability due to short half life, and extensive Phase 2 antitumoural effect. In xenograft models of range tissue types, Idronoxil enhances the cytotoxic effects of carboplatin and other antineoplastic⁽¹⁾. Preliminary evidence suggests that idronoxil may also stimulate an immune response via a NK cell pathway⁽²⁾– this may provide a complimentary effect to chemotherapy treatments and support the effects of radiotherapy both at the sites of irradiation and in tumours not irradiated.

ClinicalTrials.gov Identifier: NCT02941523

Study Design

This first-in-man study was performed in the Eastern European country of Georgia. The study consisted of 2 cohorts of 8 patients, allocated 1 of 2 doses of NOX66 – 400mg or 800mg. Patients with end stage breast, prostate, lung, ovarian or head and neck cancers were eligible for inclusion. Key inclusion / exclusion criteria are shown in Table 1. Each patient was scheduled to receive up to 27 weeks of treatment as follows:

- ◆ **Monotherapy:** 1 x 21-day treatment cycle, NOX66 administered daily for days 1-14
- ◆ **Low Dose Carboplatin (Cycles 1-3):** 3 x 28-day treatment cycles, carboplatin AUC4 administered on day 2, NOX66 administered daily for days 1-7
- ◆ **Standard Dose Carboplatin (Cycles 4-6):** 3 x 28-day treatment cycles, carboplatin AUC6 administered on day 2, NOX66 administered daily for days 1-7

Safety assessments were conducted following enrolment of 4 and 8 patients prior to continuation of recruitment (Figure 1) and ongoing throughout the study. Patients with tumours suitable for measurement by RECIST criteria were assessed by radiological scans at the commencement of Cycles 3 and 6. A protocol amendment, was incorporated during recruitment, requiring patients to be suitable for assessment by RECIST criteria allowing additional patients to be recruited to compensate for those who could not be assessed.

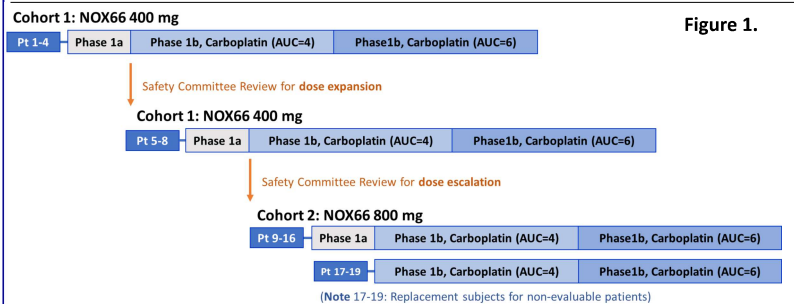


Figure 1.

Table 1. KEY Inclusion criteria	KEY Exclusion criteria
Histologically confirmed locally or metastatic advanced solid tumours	Tumour involvement Central Nervous System
At least 1 measurable lesion on CT or MRI scan	Patients who are breastfeeding or pregnant
ECOG performance scale of 0-1	Clinically significant uncontrolled cardiac disease or myocardial infarction within last 12 months; QTc of >470 msec on screening ECG
Adequate hematologic, hepatic and renal function	Uncontrolled infection or systemic disease
Minimum life expectancy of 12 weeks	Any major surgery, radiotherapy, immunotherapy within the last 21 days (palliative radiation > 2 weeks permitted)
Fertile patients agree to use of effective contraception during study and 90 days after last dose of NOX66	No concurrent chemotherapy or biologic therapy; chemotherapy with delayed toxicity within last 4 weeks
	History solid organ transplant
	Known unsuitability for treatment with carboplatin or suppository use

REFERENCES
1. DM Brown et al., (2008), *Dirus of the Future* 33(10):844-860; 2. Data on File

Study Results

Nineteen Caucasian patients (12 Female and 7 male) with median age 61–64 years and metastatic disease were recruited into the trial between 17 March 2017 and 26 October 2017, with eighteen patients receiving at least one dose of NOX66. Nine (47.3%) patients completed all cycles of therapy.

Safety: Overall 83% of patients experienced 1 or more AEs, the majority during combination therapy. The most common TEAEs were mild to severe anaemia, neutropenia and hypocalcaemia and the majority (95%) occurring during combination treatment, of which 80% were attributed to carboplatin alone. One (1) severe case of anaemia was reported during monotherapy with 800 mg dose and possibly attributed to NOX66. Grade ≥ 3 AEs occurred in 50% of patients and are identified in Table 2.

Preliminary efficacy: Of the 16 evaluable patients receiving one dose of NOX66, best radiological overall response by RECIST criteria was stabilisation of disease in 45% patients by end of study (6 cycles). One patient in 800mg dose with metastatic breast cancer had evidence of a partial overall response (Table 3).

PT.	Tumour Type	PRIOR THERAPY	STUDY THERAPY		RESPONSE		SEVERE AEs and SAEs (≥ Grade 3)		
			1 cycle Monotherapy (A)	6 cycle Combination (B)	Cycle 3	Cycle 6	Adverse Event	Related to NOX66	Related to Carboplatin
COHORT 1 (400 mg NOX66)	1 Ovarian	Chemo; Surgery	1A, 3B, 6B	NA	SD	SD	Nil	NA	NA
	2 Lung	Chemo	1A, 2B	PD	ND	ND	Back Pain	UR	UR
	3 Lung	Chemo	1A, 3B, 5Bd7	Pt decision	SD	ND	Abdominal Pain	UR	UR
	4 Lung	Chemo	1A, 1Bd15	Pt decision	ND	ND	Nil	NA	NA
	5 Breast	Chemo; Surgery	1A, 3B, 6B	NA	NE	NE	Iron deficiency	UR	UR
	6 Breast	Chemo; Surgery; HT	1A, 3B, 6Bd1	PD	SD	PD	Nil	NA	NA
	7 Breast	Chemo; Surgery; HT	1A, 3B, 6B	NA	NE	NE	Nil	NA	NA
	8 Prostate	UNK	1A, 3B, 5B	SAE	SD	NA	Sudden death	UR ^a /PR ^b	PR ^b
COHORT 2 (800 mg NOX66)	9 Prostate	Chemo; HT	1A, 3B, 6B	NA	SD	SD	Nil	NA	NA
	10 Prostate	Chemo; Surgery; HT	1A, 3B, 6B	NA	PD	PD	Nil	NA	NA
	11 Ovarian	Chemo; Surgery	1A, 3B, 6B	NA	SD	SD	Anaemia	UR	PR
	12 Ovarian	Chemo; Surgery	1A, 3Bd2	SAE	SD	ND	Infusion reaction	UR	CR
	13 Lung	Chemo; RT	1A, 2Bd15	SAE	PD	ND	GI Hemorrhage (D)	UR	UR
	14 Breast	Chemo; Surgery; HT	1A, 3B	PD	SD	ND	Nil	NA	NA
	15 Lung	Chemo	1A, 2Bd7	SAE	ND	ND	Altered consciousness/ Coma (D)	UR	UR
	16 Breast	Chemo	Not dosed	Pt decision	ND	ND	Nil	NA	NA
	17 Breast	Chemo; Surgery; HT	3B, 6B	NA	SD	PR	Nil	NA	NA
	18 Breast	Chemo; HT	3B, 6B	NA	SD	SD	Neutropenia	UR	LR
	19 Breast	Chemo; HT	3B, 6B	NA	SD	SD	Nil	NA	NA

^a Assessed by the site Investigator; # NCI CTCAE v 4.03 [†] In the opinion of the site Investigator; no autopsy conducted (per family wishes) for definitive cause of death. ^b Sponsor conservative assessment due to dosing NOX66 prior to the event
UR = unlikely related; PR = possibly related; LR = likely related; CR = certainly related
NA = not applicable; NE = non evaluable

Table 3. Overall Response (RECIST v1.1)

Dose cohort	Assessment [#] Time point	Partial Response	Stable Disease	Progressive Disease
Cohort 1	Cycle 3B	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 6B	0 (0.0)	1 (50.0)	1 (50.0)
Cohort 2	Cycle 3B	0 (0.0)	7 (77.8)	2 (22.2)
	Cycle 6B	1 (16.7)	4 (66.7)	1 (16.7)

Two patients had non-measurable target lesions at Screening and have been excluded.
[#] Assessed at the start of the cycle

Conclusion

- ◆ NOX66 has been observed to be well tolerated in patients with end stage tumours in combination with carboplatin, with one SAE of Sudden death possibly attributed to combination therapy in the absence of an autopsy and no severe or serious adverse events attributed to NOX66 use alone.
- ◆ Preliminary signals for response to treatment, combined with the observed safety profile, suggest further investigations using NOX66 800mg in combination with platinum based therapy.