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END-OF-STUDY CLINICAL DATA SHOWS BENEFIT OF NOX66

- **Data presented at ASCO Annual Meeting**
- **CEP-1 Study: NOX66 in combination with low-dose carboplatin in late-stage cancer**
- **Ability to halt cancer progress with lower incidence of chemotherapy-associated side-effects.**

Sydney, 5 June 2018: Noxopharm (ASX: NOX) today presented key end-of-study clinical data from its Phase 1b CEP-1 clinical study to the 2018 Annual Meeting of American Society of Clinical Oncology in Chicago, USA.

Program objectives

The ultimate objective of the Chemotherapy Enhancement Program (CEP) is to demonstrate that NOX66 can improve both the anti-cancer benefit and the safety of commonly used cytotoxic chemotherapy drugs.

The rationale of CEP-1 was to lower the dosage of chemotherapy to a level that generally would be well tolerated but that would be regarded as sub-therapeutic in terms of benefit, with drug-candidate, NOX66, then filling the anti-cancer benefit gap without affecting safety.

The purpose is to make chemotherapy available to a large population of patients who are not considered suitable candidates for chemotherapy because of advanced age or near end-of-life or with concurrent disease or are experiencing residual side-effects from previous courses of chemotherapy.

The reference point in CEP-1 is the broad clinical experience of the low likelihood of any clinical response to repeat chemotherapy in patients who have become unresponsive to such chemotherapy, but the high likelihood of experiencing unwanted and sometimes debilitating side-effects.

CEP-1 was a sighting study, designed to provide sufficient evidence of the validity of the approach to justify a larger study. The Study involved treating late-stage cancer patients with a combination of NOX66 plus a sub-therapeutic dosage of carboplatin over 6 months, and monitoring patients for both safety (incidence and severity of side-effects) and efficacy (scans for disease response or progression).

Trial outcome summary

On 6 March 2018, the Company reported on the outcome of the Study up to the conclusion of the first 3 cycles (3 months) of combination treatment of NOX66 + carboplatin (50% standard dose). 14 patients with evaluable disease completed those 3 cycles. 2/14 patients showed disease progression, leading to 12 patients whose cancers had been halted to undergo the final 3 cycles of treatment involving NOX66 + a slightly higher dosage of carboplatin (75% standard dosage). Of these 12 patients,

1 patient voluntarily withdrew, 1 died suddenly and 2 showed disease progression prior to reaching the end of the 6th cycle, leaving 8 patients who completed the 6 cycles of combination therapy.

Safety

Drug side-effects are classified Grade 1-5 (mild, moderate, severe, life-threatening, death). Over the whole study, there were 5 episodes of Grade 3 toxicity (back pain, abdominal pain, anaemia, neutropaenia, carboplatin infusion reaction), all of which resolved spontaneously. No other significant toxicities were reported in surviving patients and no modifications of chemotherapy or NOX66 dosage were required. There were no toxicities deemed associated with NOX66.

Efficacy

Assessment Time Point	Partial Response	Stable Disease	Progressive Disease	Total
Cycle 3	0	12	2	14
Cycle 6	1	5	4	10*

*12 patients started: 1 withdrew voluntarily; 1 sudden death

Commentary

The Company believes that the data presented today, notwithstanding the small number of patients, provides evidence that the CEP approach is valid. From the 14 patients who were able to complete the initial 3 cycles of combination therapy, 6 patients finished all 6 cycles with stable disease or better (1 partial response). These 6 patients, as well as those surviving patients that eventually suffered disease progression, tolerated the combination therapy well, with the small number of severe toxicities self-resolving.

The Company now plans to conduct a larger multi-national Phase 2 study to test this promising approach to late-stage chemotherapy in a larger number of patients receiving different chemotherapy drugs.

Dr Graham Kelly, Noxopharm CEO, said, “To put this ASCO data into context, it comes from patients with end-stage disease. These are patients with extensive secondary disease and with a limited life-span, having undergone multiple rounds of chemotherapy and finally reaching a point of being unresponsive to standard therapy. Patients at this advanced stage of the disease process typically have considerable morbidity from the cancer, and often comorbidity from other diseases.”

“It is in this context that we are cautiously optimistic in seeing what we believe is our therapeutic dosage of NOX66 being able to salvage almost half of the patients. We were able to halt growth of cancer over the 7-month period that the Study ran in a significant number of patients, where few patients normally would have been expected to survive. And importantly, these patients finished the study in generally good health, having experienced little toxicity from the chemotherapy.”

“A larger controlled study now will need to be done comparing NOX66 + low-dose chemotherapy with standard dose chemotherapy. We would expect the control arm using a standard dosage of chemotherapy drugs in any such study to be associated with significant levels of toxicity, including the high probability of painful nerve damage and hearing loss, and with only limited prospects of achieving no disease progression over 7 months,” Kelly added.

The 800 mg NOX66 dosage gave a better response rate than the 400 mg dosage, and the Company anticipates this being the dosage that it will take forward. Planning for a multi-national Phase 2 study will commence shortly, with a study expected to commence about mid-2019.

Noxopharm has a major interest in using NOX66 to enhance radiotherapy, however, for those patients where radiotherapy either isn’t appropriate or isn’t practical, then the CEP-1 data suggests that NOX66 has the potential to offer a way of providing effective chemotherapy while minimising the risk of unwanted side-effects.

The ASCO data will be available today on the Noxopharm website (www.noxopharm.com) and visiting the News section and then the Publications page.

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About NOX66

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 including sphingosine kinase and PI3 kinase that regulate cell pro-survival mechanisms and which are over-expressed in cancer cells, as well as inhibiting external NADH oxidase Type 2 (ENOX 2) which is responsible for maintaining the transmembrane electron potential (TMEP) in the plasma membrane of cancer cells and whose expression is limited to cancer cells. Inhibition of these enzymes results in disruption of key downstream pro-survival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapies. Idronoxil also increases the activity of human NK cells.

About the CEP-1 Study

CEP-1 involved patients with progressive, late-stage, metastatic cancer (breast, ovarian, lung, prostate). All patients had disease that had stopped responding to standard chemotherapies, including platinum-based drugs such as carboplatin. Study treatment involved a 21-day safety run-in of NOX66 monotherapy alone, followed by 6x 1-monthly cycles of combination chemotherapy (NOX66 + carboplatin). Each cycle involved a single intravenous injection of carboplatin combined with 7 days of NOX66. The first 3 cycles used a dose of carboplatin half of the standard dose (AUC4 monthly). Patients who showed no disease progression after the first 3 cycles, then underwent another 3 cycles with a dose of carboplatin three-quarters of the standard dose (AUC6 monthly). Two different dosages of NOX66 were used (400 and 800 mg daily). Patients were assessed clinically for the incidence of side-effects (Grade 1-5) and scanned at 0, 3 and 6 months for their disease status (complete response, partial response, stable disease, progressive disease). 19 patients were enrolled: 17 had evaluable disease and 2 had non-evaluable disease (assessed for safety, but not efficacy signals). Of the 17 evaluable patients, 6 were enrolled in Cohort 1 (400 mg NOX66) and 11 in Cohort 2 (800 mg NOX66).

About RECIST

Response Evaluation Criteria in Solid Tumors (RECIST) is an objective means of determining whether a cancer is improving ('responding'), staying the same ('stable disease') or worsening ('progressive disease'). Patients are scanned (usually CT or MRI) and all tumor lesions identified and counted, with up to 10 lesions ('target lesions') measured along their longest diameter (LD). Complete response: disappearance of all target and non-target lesions. Partial response: at least a 30% decrease in the sum of the LDs of target lesions. Stable disease: not qualifying as either partial response or progressive disease, plus persistence of at least 1 non-target lesion. Progressive disease: at least a 20% increase in the sum of the LDs of target lesions, clear progression of non-target lesions, and appearance of new lesions.

About carboplatin toxicity

Carboplatin is a platinum-based cytotoxic chemotherapy drug. Its side-effects include thinned or brittle hair, anaemia, low white blood cells (neutropaenia) loss of appetite, fatigue, stomach pain, diarrhoea, nausea, constipation, vomiting, numbness or tingling in the fingertips, hearing loss, pain in back, change in taste, mouth sores, kidney damage, infection.

About Noxopharm

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney and Hong Kong. The Company has a primary focus on the development of drugs to sensitise cancer cells to radiotherapy and chemotherapy. NOX66 is the first pipeline product, with later generation drug candidates under development.

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