ASX Announcement | 9 November 2020
Noxopharm Limited (ASX:NOX)

Veyonda® To Be Tested In Combination With Opdivo® In Trial

Highlights:

- **Noxopharm to proceed with IONIC Phase 1b study**
- **Pilot study testing ability of Veyonda® to boost efficacy of Bristol Myers Squibb's immuno-oncology drug, nivolumab (Opdivo®).**
- **Primary rationale to test the ability of Veyonda® to restore immune function within tumours**
- **Study in three Australian hospitals; under direction of eminent medical oncologist, Professor Paul De Souza**

Sydney 9 November 2020: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to announce that NOX have joined with Principal Investigator, Professor Paul De Souza, and three Sydney hospitals in a pilot study (IONIC-1) to explore the ability of Veyonda® to boost the effectiveness of Bristol Myers Squibb's nivolumab (Opdivo®) for the treatment of cancer.

The program known as IONIC stands for **I**mmuno-**O**ncology with Veyo**N**da and **I**mmune **C**heckpoint inhibitors.

Immune checkpoint inhibitors such as nivolumab have revolutionised the treatment of some cancers with what can be dramatic life-saving benefits. However, some patients have inherent resistance to immune checkpoint inhibitors and the IONIC-1 study will investigate whether Veyonda is able to overcome this resistance in patients with cancers such as breast, ovarian, prostate and sarcoma cancers.

Research points to a key limiting factor being the lack of competent immune function within cancer, with individual tumours actively expelling immune cells. Restoring that immune function is referred to commonly as converting tumours from COLD to HOT and is a major current goal within the pharmaceutical industry. There is growing evidence of this effect being a key anti-cancer function of Veyonda.

The IONIC-1 pilot study will investigate the combination of Veyonda and nivolumab (Opdivo®) for the treatment of a range of tumour types in approximately 30 cancer patients. Following Ethics Committee approvals, it is anticipated that the first patients will be recruited early in the New Year.

Professor De Souza BScMed MB BS MPH PhD FRACP is the Principal Investigator. Professor de Souza is an eminent oncologist and thought leader with extensive experience in cancer drug development. He holds the positions of Head of School and Dean of Medicine at the University of Wollongong, Conjoint Professor at the University of NSW and Foundation Chair of Medical Oncology at Western Sydney University, as well

as being a practicing medical oncologist at Sydney's Liverpool Hospital, St George Private Hospital, and Southside Cancer Care Centre. He also runs a research laboratory at the Ingham Institute for Applied Medical Research.

Prof De Souza said 'I'm excited to be working with Noxopharm and Bristol Myers Squibb on this study. Checkpoint inhibitors have made a tremendous difference to some patients with advanced cancer and if we can increase the number of patients that respond through the addition of Veyonda to their treatment regimen, we will make a significant impact, not only to those individuals, but also on the oncology landscape.'

The checkpoint inhibitor market encompassing PD-1, PD-L1 and CTLA-4 inhibitors is a multi-billion-dollar market with rapid year on year growth, currently dominated by two major global pharmaceutical companies, one of which is Bristol Myers Squibb.

The IONIC-1 study is an investigator-initiated study and will have no major impact on the Company's R&D costs with a financial contribution being limited largely to the provision of Veyonda®.

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.

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About IONIC-1
IONIC-1 is a pilot-study exploring the safety and efficacy signals of Veyonda in combination with Opdivo for patients with solid tumours. There will be two cohorts: one cohort that has progressed on Opdivo and one cohort with a cancer type that is not usually responsive to IO-therapy and treatment naïve to Opdivo. Both cohorts will be enrolled in parallel. Approximately 30 patients will participate in the study. The first part of the study will be a dose-escalation design with Veyonda doses ranging from 1200 mg to 2400 mg. The second part will be a dose expansion of the highest dose that is safe and well tolerated. The Opdivo dose will be 240 mg intravenously once every 14 days for both cohorts.

About Veyonda®
Veyonda® is a second-generation immuno-oncology drug candidate based on selective inhibition in cancer cells of the pro-survival secondary messenger, sphingosine-1-phosphate (S1P). The body uses a gradient of S1P levels (high to low) to move immune cells between blood and tissues. Cancers express high levels of S1P, reversing that gradient and thereby expelling immune cells from tumours. By inhibiting S1P in tumours, Veyonda® is designed to restores a normal gradient, thereby allowing immune cells to repopulate tumours in a so-called COLD to HOT conversion.

About Nivolumab
Nivolumab (Opdivo) is an immune checkpoint inhibitor. It is an antibody against human programmed death receptor-1 (PD-1). It has regulatory approval in Australia for melanoma, Hodgkin's lymphoma and cancer of the lungs, kidneys, head and neck, liver, bladder and colon .

About Noxopharm

Noxopharm Limited (ASX:NOX) is an Australian clinical-stage drug development company focused on the treatment of cancer and septic shock. Noxopharm also is the major shareholder of US biotechnology company Nyrada Inc (ASX:NYR).

To learn more, please visit: 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 Enquiries
Julia Maguire
The Capital Network
E: julia@thecapitalnetwork.com.au
T: + 61 2 8999 3699

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