Veyonda® and Opdivo® IONIC Study First Patient Dosed

Highlights

- First patient dosed with combination Veyonda® and Bristol Myers Squibb checkpoint inhibitor, Opdivo® (nivolumab)
- Aim is to use Veyonda to overcome drug resistance to immune checkpoint inhibitors such as Opdivo
- Success would expand multi-billion dollar drug sector considerably and deliver major shareholder value.

Sydney 26 October 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) announces the commencement of treatment of the first patient into the IONIC-1 trial supported by Noxopharm and Bristol Myers Squibb (BMS).

A positive outcome would mean Veyonda resulting in more cancer types and more patients being responsive to immune checkpoint inhibitor (ICI) therapy, opening up the multi-billion-dollar ICI market to Noxopharm.

The IONIC-1 trial (*ASX: 9 Nov 2020, 19 Mar 2021*) is a pilot Phase 1 trial in approximately 30 cancer patients, combining Veyonda® with the BMS drug, Opdivo® (nivolumab), for the treatment of a range of tumour types. The trial is being conducted at a number of sites in Australia.

ICIs such as nivolumab have had impressive results in some patients with a limited number of cancer types, but remain inactive in most cancers. The aim of the study is to increase the activity of nivolumab by using Veyonda to overcome tumour resistance to ICI therapy.

The ICI market currently has annual sales of about US$20 billion. Market analysts predict this to rise to US$45 billion by 2025 through strong year-on-year growth. Increasing the number of cancer types that respond to ICI therapy from the current small number would expand the market even more, leaving any company with the technology to help achieve that goal in a highly valuable position. The ICI market is dominated by two major global pharmaceutical companies, one of which is Bristol Myers Squibb.

Noxopharm Chief Medical Officer Dr Gisela Mautner commented, *"If we can improve the performance of ICIs by the addition of Veyonda, it could make a massive impact, improving outcomes for cancer patients worldwide. It is exciting that this study is now underway in Australia and we look forward to updating the market as the study progresses."*

The IONIC-1 Trial

Under the stewardship of Principal Investigator, medical oncologist Professor de Souza, BScMed MB BS MPH PhD FRACP, the study will be comprised of two patient groups. One group will not have had previous nivolumab treatment because they have cancers considered unsuitable for ICI use because of inherent ICI-resistance, the second group will be patients whose cancers were treated with an ICI but subsequently displayed resistance to ICI treatment.

The trial endpoints are

(i) safety and tolerability of the drug combination
(ii) the therapeutic dose of Veyonda
(iii) efficacy outcomes
(iv) effect on various blood biomarkers.

The Company regards a successful outcome as the combination treatment achieving stable disease or better in patients with progressive disease and to have done so without creating additional safety issues compared to ICIs on their own.

Immune checkpoint inhibitors and Veyonda

Immune checkpoints are proteins expressed on the surface of cancer cells, forming a protective shield that blocks immune cells (T-cells) from attacking them. Immune checkpoint proteins are one of the key defences cancer cells use to avoid destruction by the immune system, allowing the cancer to survive and spread around the body.

Drugs such as nivolumab nullify this shield, opening the cancer cell up to being killed by immune cells. Resistance to this class of drug is thought to be associated with a lack of immune cells within individual tumours, with loss of the protective shield devalued by the absence of immune cells to take advantage of the situation.

Veyonda is a first-in-class, selective inhibitor of sphingosine-1-phosphate (S1P), reversing the S1P gradient believed responsible for the expulsion of immunes cell from tumours and allowing repopulation of tumours with active immune cells.

The IONIC-1 trial is predicated on the basis that this so-called COLD to HOT conversion of tumours will prove to be the essential co-factor with nivolumab for effective immune control of cancer.

The use of Veyonda in this way is the subject of patent applications in numerous territories world-wide.

-ENDS-

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.

About IONIC-1
IONIC-1 is a pilot-study exploring the safety and efficacy signals of Veyonda in combination with nivolumab for patients with solid tumours. There will be two cohorts: one cohort of patients that has progressed on ICIs and one cohort with patients who are treatment naïve to ICIs. 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 nivolumab dose will be 240 mg intravenously once every 14 days for both cohorts.

About Noxopharm

Noxopharm Limited (ASX:NOX) is an Australian clinical-stage drug development company focused on the treatment of cancer and cytokine release syndrome (septic shock).

Veyonda® is the Company's first pipe-line drug candidate currently in Phase 2 clinical trialling. Veyonda® has two main drug actions – a moderating effect on the ceramide/sphingosine-1-phosphate balance and inhibition of STING signalling. Activity against the former target contributes to its dual-acting oncotoxic and immunomodulatory functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiation therapies and immune checkpoint inhibitors. Activity against the latter target provides an anti-inflammatory effect, as well as contributing to an anti-cancer action, but also potentially blocking septic shock.

Noxopharm is running comprehensive drug discovery programs in both oncology and inflammation, and is the major shareholder of US biotechnology company, Nyrada Inc (ASX:NYR), active in the areas of drug development for cardiovascular and neurological diseases.

To learn more, please visit: noxopharm.com

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Forward Looking Statements

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