ASX Announcement | 1 September 2020
Noxopharm Limited (ASX:NOX)

Veyonda® COVID-19 Study Approved For Immediate Start

Highlights

- Official approval granted for use of Veyonda® in hospitalised COVID-19 patients in Europe
- NOXCOVID-1 study to commence immediately with approximately 40 patients to be treated
- Important study as Veyonda® is believed to be the first drug tested in COVID-19 patients that blocks an emerging key trigger (excessive STING response) of long-term disability and death in COVID-19 patients

Sydney, 1 September 2020: Australian drug development company **Noxopharm Limited (ASX: NOX)** today announces the commencement of a clinical study of Veyonda® in COVID-19 patients. Following review by expert panels, official approval has been granted for immediate commencement of the Phase 1 NOXCOVID-1 study.

This is an important milestone for the Company. It also represents an important medical milestone in being the first known use of a drug in COVID-19 patients that inhibits a target (STING pathway) increasingly being incriminated as a leading cause of death and long-term disability in these patients.

Noxopharm has previously (*19 Jun 2020, 21 Apr 2020, 1 Apr 2020*) provided information on Veyonda® and what it believes to be its potential to prevent the progression of COVID-19 disease via the STING pathway into the phenomenon known as a 'cytokine storm' leading onto septic shock.

The NOXCOVID-1 study

NOXCOVID-1 will involve approximately 40 COVID-19 patients in hospitals in Ukraine and Moldova, two countries currently experiencing high rates of infection and hospitalisation.

A range of doses of Veyonda® will be administered to patients hospitalised with moderate symptoms who are at high risk of tipping over into a cytokine storm and developing septic shock. Typically, these patients are sick enough to require hospitalisation, but do not yet have such severe symptoms that they require ICU care or mechanical ventilation.

Patients will be treated with Veyonda® for at least 14 days and may receive treatment for up to 28 days if required. The safety and tolerability of the medication in patients with poor lung function will be measured, as well as the drug's ability to prevent patients progressing into a cytokine storm and septic shock. One of the key endpoints is the effect of treatment on blood cytokine levels, which will be assayed in an Australian laboratory.

Training of the medical personnel at the study sites has been completed and now that approval has been granted, supplies for the study are being shipped without delay. The study will commence immediately and patients will be enrolled until late-October 2020. Findings of the study are anticipated to be released in early-2021.

Dr Gisela Mautner, Noxopharm Chief Medical Officer, said: "This is an important step in potentially bringing to market a medication that could reduce the devastating worsening lung function and multi-organ failure that afflicts a number of COVID-19 sufferers. There is growing scientific evidence that excessive STING signalling is behind the cytokine storm causing severe disease and even death in COVID-19 patients. Therefore, the Company is excited to be in a position to put this theory into practice and hopefully help to reduce the terrible impact of this pandemic."

Graham Kelly, Noxopharm CEO, said: "Increasingly it looks likely that the world is going to have to learn to live with the SARS-CoV-2 virus, including needing to have effective therapies to deal with the 5% or so of patients who contract the virus and whose lung failure puts them at risk of developing a cytokine storm and its associated serious clotting disorders. The upcoming NOXCOVID-1 study potentially could position Veyonda® as a front-line therapy for those patients, irrespective of whether an effective and safe vaccine is developed."

The Company will consider its next step after reviewing the final NOXCOVID-1 data. Noxopharm remains in discussion with the U.S. FDA on conducting a clinical study in the U.S., with NOXCOVID-1 serving as a pilot, proof-of-principle study.

Graham Kelly, CEO and Executive Chair, has approved the release of this document to the market on behalf of the Board of Directors.

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About Noxopharm

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

Veyonda® is the Company's first pipe-line drug candidate currently in Phase 2 clinical trialling. Veyonda® has two main drug actions – inhibition of sphingosine kinase and inhibition of STING signalling. Activity against the former target contributes to its dual-acting oncotoxic and immuno-oncology functions designed to enhance the effectiveness and safety of standard oncology

treatments, i.e., chemotherapy, radiotherapy and immune checkpoint inhibitors. Activity against the latter target provides an anti-inflammatory effect, also contributing to an anti-cancer action, but also potentially blocking sepsis.

Noxopharm also is the major shareholder of US biotechnology company Nyrada Inc (ASX:NYR).

About Veyonda® and cytokine storm

Idronoxil, the active ingredient in Veyonda®, blocks the STING signalling pathway[5]. This immune pathway is induced upon lung damage,[6] and is responsible for triggering the production of a range of cytokines, including IL-6, IL-10 and IP-10, which are responsible for the cytokine storm which can lead to septic shock and potentially death.

References

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