



## **NOXCOVID Study Advancing Following Clinical Review**

**13 January 2021 Sydney, Australia: Australian clinical stage drug development company, Noxopharm Limited (ASX:NOX),** announces that the latest formal review by the NOXCOVID-1 Safety Steering Committee has cleared it to advance to the fifth and final dosage cohort.

The Committee is independent of the Company, with investigators unanimously voting to move to the 1800 mg dose after they reviewed the safety profile of Veyonda<sup>®</sup> in 12 patients from Cohorts 3 and 4 (involving 800 and 1200 mg Veyonda respectively). The Company regards this as a highly encouraging outcome given the advanced nature of COVID-19 disease in these study patients, in particular suffering serious lung dysfunction.

The Company will be reporting formally on efficacy in due course, with the overall objective being to use Veyonda to block the cytokine release syndrome (so-called 'cytokine storm') that leads to patients requiring intensive care, and is a primary cause of the multi-organ damage responsible for much of the long-term disability and death in COVID-19 patients.

**Noxopharm CEO, Dr Graham Kelly,** said, "Patients we are treating are at the stage of COVID-19 disease generally associated with high rates of deteriorating lung function requiring intensive care. While early days, the progress of the trial is serving to boost our confidence that Veyonda is capable of meeting its primary objective of blocking the cytokine release syndrome causing that rapid deterioration, and doing so in a well-tolerated and minimally-intrusive way."

The issues of drug safety and ease of administration look set to become major issues as the pandemic evolves. The emerging situations in the UK and parts of the U.S. are causing alarm, with hospitals reportedly being overwhelmed to the point of having insufficient ICU beds and staff to meet demand. The need for effective triage treatments able to be administered under minimal medical supervision in both developed and developing countries where lack of ICU facilities is even more concerning, looks set to grow exponentially. The Company sees Veyonda as having the properties to meet this need.

Kelly said, "Noxopharm sees a commitment to the NOXCOVID trial as adding considerable commercial value to Veyonda, apart from obvious humanitarian reasons. With an estimated 11

million deaths each year from septic shock<sup>1</sup>, the need to block cytokine release syndrome effectively and safely goes well beyond the current pandemic with its estimated approximately 2 million deaths to date. While Veyonda remains the Company's current spearhead drug in the septic shock field with a potential major role to play in the pandemic, our subsidiary Pharmorage in collaboration with Hudson Institute of Medical Research and the Australian National University is underway in developing a drug purpose-built for septic shock across all situations."

1. *Rudd KE et al (2020). Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. Lancet 395:200-211*

*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.*

**-ENDS-**

#### **About NOXCOVID-1**

NOXCOVID-1 is a Phase I study aiming to demonstrate that in COVID-19 patients who are at risk of developing a cytokine storm and septic shock, that Veyonda:

- is well tolerated, and
- can halt disease progression into the cytokine release syndrome and septic shock.

NOXCOVID-1 is a two-part study comprising dose-escalation followed by dose-expansion. The dose-escalation phase comprises 5 patient cohorts (400, 600, 800, 1200 and 1800 mg Veyonda daily dosages). The dose-expansion phase will use the dose determined to be the optimal. The study is focusing on safety and proof-of-principle endpoints (biomarker and clinical responses). Approximately 40 patients will be recruited who have been admitted to hospital for respiratory insufficiency (not requiring artificial ventilation) associated with the SARS-CoV-2 virus. Patients will be treated for between 14-28 days depending on their clinical response.

The pharmacological rationale is that the first-in-class anti-inflammatory action of Veyonda via the STING signaling pathway will block the release of a broad range of cytokines including a number of interleukins. The aim is to prevent a cytokine onslaught that inflicts tissue damage in the lungs and other major organs, aggravating lung damage and requiring mechanical ventilation and potentially causing death.

Veyonda is not intended to replace other potential anti-inflammatory treatments like dexamethasone that may provide a clinical benefit in patients with more advanced disease already experiencing a cytokine storm.

#### **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 trialing. Veyonda® has two main drug actions – indirect inhibition of sphingosine kinase and STING signaling. The former function contributes to its dual-acting oncotoxic and immuno-oncology functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiotherapy and immune checkpoint inhibitors. The latter function provides an anti-inflammatory effect, also contributing to an anti-cancer action, but also blocking the cytokine release syndrome.

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

To learn more, please visit: [noxopharm.com](http://noxopharm.com)

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**Forward Looking Statements**

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as “aim”, “anticipate”, “assume”, “believe”, “continue”, “could”, “estimate”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “plan”, “should”, “target”, “will” or “would” or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company’s control that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement.