ASX Announcement | 2nd October 2020
Noxopharm Limited (ASX:NOX)

First COVID-19 Patient Treated in Veyonda® Study

Highlights:

- **First NOXCOVID-1 clinical trial patient begins treatment with Veyonda®**
- **Veyonda® being assessed for use in hospitalized patients suffering from moderate COVID-19 disease**
- **Aim is to demonstrate Veyonda® is well tolerated and able to stop worsening of the disease**
- **Significance lies in first known test of STING signaling inhibition in preventing destructive hyper-inflammatory response in COVID-19 disease**

Sydney 2 October 2020: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to announce the enrolment and treatment of the first patient into the Phase 1 NOXCOVID-1 study examining the potential use of Veyonda® in blocking the rapid progression of COVID-19 disease from moderate to severe level.

Most COVID-19 patients hospitalised with moderate lung dysfunction requiring low oxygen support recover uneventfully. However, a proportion progress into requiring intensive care and mechanical ventilation, with that proportion rising with increasing age and incidence of co-diseases such as diabetes. The aim of the NOXCOVID-1 study is to test the ability of Veyonda® to stop that deterioration in high-risk patients both safely and effectively.

As reported previously (21 Apr 2020, 19 Jun 2020, 1 Sept 2020), recent pre-clinical research has shown that at least part of the anti-cancer action of Veyonda® comes via a novel anti-inflammatory action involving the STING signaling pathway. With COVID-19 disease increasingly being seen as a hyper-inflammatory response to damage caused by the virus, recent Australian research conducted by Hudson Institute of Medical Research in Melbourne suggests that the novel anti-inflammatory action of Veyonda® could potentially prevent progression of COVID-19 disease.[1-3]

NOXCOVID-1 is being conducted in a number of hospitals in Eastern Europe. This first patient is hospitalised in the Republic of Moldova, a country with ongoing growth in COVID-19 cases.[4] Patients will be monitored closely by experienced medical investigators and the whole trial overseen by a UK-based contract research organisation.

Chief Medical Officer Gisela Mautner said this week ''It is a testament to the skill of our scientific team and our external research collaborators that we have been able to identify through our pre-clinical work the potential application of Veyonda® in the treatment of COVID-19, and have been able to use our prior oncology-focused work to address this new and urgent global need. As an agile biotech company

Noxopharm and its study partners have worked to expedite the NOXCOVID-1 study, leading to the very short timeframe between study approval and implementation with the treatment of the first patient hospitalised with COVID19. It is our hope that Veyonda® will lessen the severity of COVID-19 and improve the recovery of affected patients worldwide.''

The NOXCOVID-1 trial will enrol up to approximately 40 patients, with enrolment due to be completed before the end of the year. Patients will be treated with Veyonda® between 14-28 days depending on clinical response using a two-step dose-escalation and -expansion trial design. The endpoints will include a large number of safety and efficacy parameters standard for COVID-19 trials. As a pilot study, the Company anticipates releasing interim clinical response data on a rolling basis over the next 3-4 months.

Noxopharm is making a commitment to its NOXCOVID program on the basis that until the world is certain of the efficacy and safety of vaccines and the proportion of the community willing to be vaccinated, there is an urgent need to continue to search for therapies that will lessen the rates of death and long-term disabilities from COVID-19.

References

1. Berthelot J-M, and Liot E. COVID-19 as a STING disorder with delayed over-secretion of interferon-beta. 2020. EBioMedicine 56. https://doi.org/10.1016/j.ebiom.2020.102801
2. Deng X, Yu X, Pei J. Regulation of interferon production as a potential strategy for COVID-19 treatment. 2020. arXiv preprint arXiv:2003.00751,
3. Berthelot J-M, Drouet L and Liot E. Kawasaki-like diseases and thrombotic coagulopathy in COVID-19: delayed over-activation of the STING pathway? 2020. Emerging Microbes & Infections, 9:1, 1514-1522, DOI: 10.1080/22221751.2020.1785336.
4. https://covid19.who.int/region/euro/country/md

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 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., chemotherapies, 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).

To learn more, please visit: noxopharm.com

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