Noxopharm's potential COVID-19 treatment - Lodges pre-IND Submission with FDA for Veyonda® Clinical Trial

Marking a step forward, clinical-stage drug development company Noxopharm (ASX:NOX) has lodged a pre-IND (Investigational New Drug) submission with the U.S. Food and Drug Administration (FDA) for a Veyonda® clinical trial in COVID-19 (SARS-CoV-2) patients.

The basis of Noxopharm's pre-IND submission to the FDA is the potential of Veyonda® to inhibit the cGAS-STING signalling pathway, which could contribute to the onset of cytokine storms and septic shock events in COVID-19 patients. Moreover, the submission relies on a response to a package provided to the FDA outlining the rationale for carrying out a clinical trial with a cGAS-STING signalling inhibitor.

Notably, Noxopharm's pre-IND submission holds the potential for conversion into a fully expedited IND, which is a new option offered to COVID-submissions of utmost importance that significantly minimises the complexity and time of the FDA review process.

Given the current uncertainty around the pandemic, Noxopharm expects to receive FDA decision shortly.

Veyonda® with the Potential to Inhibit cGAS-STING Signalling Pathway

Pre-clinical research undertaken by the Hudson Institute of Medical Research has demonstrated that the potent inhibition of the cGAS-STING signalling pathway is potentially one of the key anti-cancer mechanisms of action of Veyonda®'s active ingredient, idronoxil.

The pre-clinical discovery led Noxopharm and the Hudson Institute to believe that Veyonda® possesses the potential to prevent hyperinflammation originating from the infection, that is considered responsible for many of the deaths in COVID-19 patients.

Noxopharm believes Veyonda®'s potential to inhibit the cGAS-STING signalling pathway can offer a prospective treatment of septic shock in COVID-19 patients. Septic shock is a condition associated with clotting and inflammatory problems and deemed to be causing multi-organ failures and deaths in COVID-19 patients.

With the inhibition of cGAS-STING signalling pathway, Veyonda® provides an opportunity to block a wide array of cytokines at their source, possibly diminishing the severity of septic shock and the number of patients dying from it, or potentially even blocking it entirely.

How Could the cGAS-STING Signalling Pathway Trigger Cytokine Storms?

The cGAS-STING signalling pathway is part of a primitive defence mechanism that detects the presence of an invading virus by activating the production of cytokines and thereby alerts the body's immune system to fight the infection. This pathway contributes to an immune response that facilitates uneventful recovery of most COVID-19 patients.

However, in some cases wherein patients develop breathing problems resulting in low oxygen levels, the resulting tissue damage in significant organs instigates an excessive and second wave of cGAS-STING signalling, leading to the onset of a 'cytokine storm', inducing blood clotting problems and intensifying existing tissue damage. These actions promote further organ damage and form the basis of septic shock.

In COVID-19 patients, the cytokine storm is triggered by mounting tissue damage coupled with poor oxygen levels (hypoxia) emerging from inadequate lung function. Moreover, high levels of clotting factors and cytokines are thought to be implicated in the deaths of COVID-19 patients.

Noxopharm's Proposed Veyonda® Clinical Trial in COVID-19 Patients		
Phase 1	**Phase 2**	**Phase-3**
Dose-Response	Dose-Confirmation	Dose-Expansion (comparison of Veyonda® with existing standard of care treatment)

Numerous COVID-19 clinical trials are being carried out with drugs blocking only individual components of the 'cytokine storm', such as IL-6 and TNF-alpha, across the world. It is believed Noxopharm's potential drug candidate may block a broad range of the components involved in the 'cytokine storm' events observed in COVID-19 patients.

Noxopharm believes its approach of blocking the 'cytokine storm' process at its roots, by inhibiting the cGAS-STING signalling pathway, is a more optimal one than its competitors. By using Veyonda® to block the cGAS-STING signalling pathway, Noxopharm aims to reduce the burden on intensive care units and lower mortality rates in COVID-19 patients.

NOX traded at $0.225 on 25 March 2020 (11:55 AM AEST).

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