Noxopharm (ASX:NOX) lodges Veyonda pre-IND submission with U.S. FDA - The Market Herald

Executive Chairman & CEO, Graham Kelly
Source: Switzer Financial Group

- Noxopharm (NOX) has lodged its pre-Investigational New Drug (pre-IND) submission with the U.S. Food and Drug Administration (FDA) for clinical trials of Veyonda in patients with COVID-19
- The proposed trials will aim to establish Veyonda as an effective treatment of septic shock, which is thought to contribute to organ failure and death in infected people
- Successful approval of the pre-IND is expected to reduce the time and complexity of the FDA's full review process
- The clinical study will involve three steps; dose response, dose confirmation and dose expansion
- The final stage, dose expansion, will compare Veyonda with the current standard of care treatments
- Despite the announcement, Noxopharm is down 4.35 per cent on the market today, trading for 22 cents per share

Noxopharm (NOX) has lodged its pre-Investigational New Drug (pre-IND) submission with the U.S. FDA for clinical trials of Veyonda in patients with COVID-19.

Based in New South Wales, the company believes that Veyonda has the potential to act as an effective treatment of septic shock in infected people. Septic shock is associated with inflammatory and clotting problems, and is thought to be a factor in multi-organ failure and death in COVID-19 patients.

Veyonda works by inhibiting cGAS-STING signalling, which alerts the body to the presence of a virus by triggering cytokine production. Pre-clinical research conducted by the Hudson Institute of Medical Research attributed this to the action of idronoxil – the active ingredient in Veyonda.

While cGAS-STING signalling is vital in generating an immune response, it has led to some complications in a small proportion of patients.

Respiratory problems, which have been strongly associated with COVID-19, lead to low oxygen levels in the blood. The resulting tissue damage has, on occasion, led to a second and excessive wave of cGAS-STING signalling, giving way to a 'cytokine storm'. This has then amplified the existing tissue damage and induced further blood clotting problems.

Due to the urgency of the global COVID-19 situation, positive pre-IND evaluation by the U.S. Food and Drug Administration would lead to a fully expedited Investigational New Drug approval. This is a new option offered to COVID-related submissions, and significantly reduces the time and complexity of the full FDA review process.

Noxopharm's proposed study involves three key stages: dose response, dose confirmation and dose expansion. The final stage, dose expansion, will compare Veyonda with the current standard of care treatments.

Several clinical trials are currently underway related to the 'cytokine storm', including IL-6 and TNF-alpha. That said, Noxopharm's pre-IND submission claims that by inhibiting the cGAS-STING pathway, Veyonda has the ability to block a wider range of cytokines at their source. This is thought to reduce the severity of septic

shock, or potentially prevent it entirely.

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