US FDA approval sought for clinical trial for potential COVID-19 treatment

Mirage News

Biotech company Noxopharm is seeking approval from the US FDA for a clinical trial in COVID-19 patients of an end-stage prostate cancer drug, following a discovery by Hudson Institute researchers that it could act as an anti-inflammatory.

> Dr Michael Gantier

Announced earlier this month, researchers found in laboratory tests that the active ingredient in the medication, idronoxil, could block the production of several pro-inflammatory proteins, known as cytokines. These proteins are believed to be involved in a 'cytokine storm', which causes a severe inflammatory response believed to be responsible for most of COVID-19 deaths.

Noxopharm announced to the ASX on Tuesday, 21 April 2020 it is now seeking US FDA approval to test the drug in COVID-19 patients. Initially, Noxopharm planned to formulate idronoxil in an oral form called NOX-19 to distinguish it from its cancer drug, Veyonda. However, the company will proceed instead with Veyonda®, given that product's current Investigational New Drug (IND) status.

Hudson Institute researcher Dr Michael Gantier, Research Group Head of the Nucleic Acids and Innate Immunity Laboratory, identified the previously unknown functions of idronoxil.

> "Our laboratory studies indicated that idronoxil inhibits inflammatory cytokines produced in the context of tissue damage seen in acute respiratory distress syndrome (ARDS)," Dr Michael Gantier said.
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> "Our findings suggest that idronoxil blocks the process of inflammatory cytokine production, along with other key influencers of organ failure," he said.

In an announcement to the ASX on 20 April, 2020, Graham Kelly PhD, Noxopharm CEO, said, "The need to prevent the phenomena of cytokine storm and septic shock – organ failure – in COVID-19 patients looks likely to remain for some considerable time. It may remain a long-term need should development of an effective vaccine prove challenging.

"Proving the value of Veyonda® to COVID-19 patients is both a humanitarian and regulatory approval opportunity that we cannot overlook."

He said Veyonda® also has the advantage of having addressed the issue of safety by proving to be well-tolerated in patients with advanced cancers and poor quality of life.

COVID-19 can progress from a mild disease into an overwhelming and lethal later-stage condition following a severe inflammatory response from the body's immune system. This can lead to ARDS, respiratory, heart and kidney failure, blood

clotting problems and septic shock.

The triggers of the severe hyper-inflammatory response in some COVID-19 patients is not fully understood. However, it is known to be associated with a 'cytokine storm'. Normally, several proteins known as pro-inflammatory cytokines help to regulate a healthy inflammatory process in the body to protect against infection or illness. However, in a 'cytokine storm', their levels are excessively high in the blood.

/Public Release. View in full here.