Noxopharm receives FDA green light to progress towards Veyonda® trial

Shares in Noxopharm Ltd (ASX:NOX) traded more than 40% higher on Tuesday afternoon after the company received advice from the US Food and Drug Administration (FDA) that it should lodge a pre-Investigational New Drug (pre-IND) submission for a clinical trial of Veyonda® in patients with SARS-CoV-2 (COVID-19) infection.

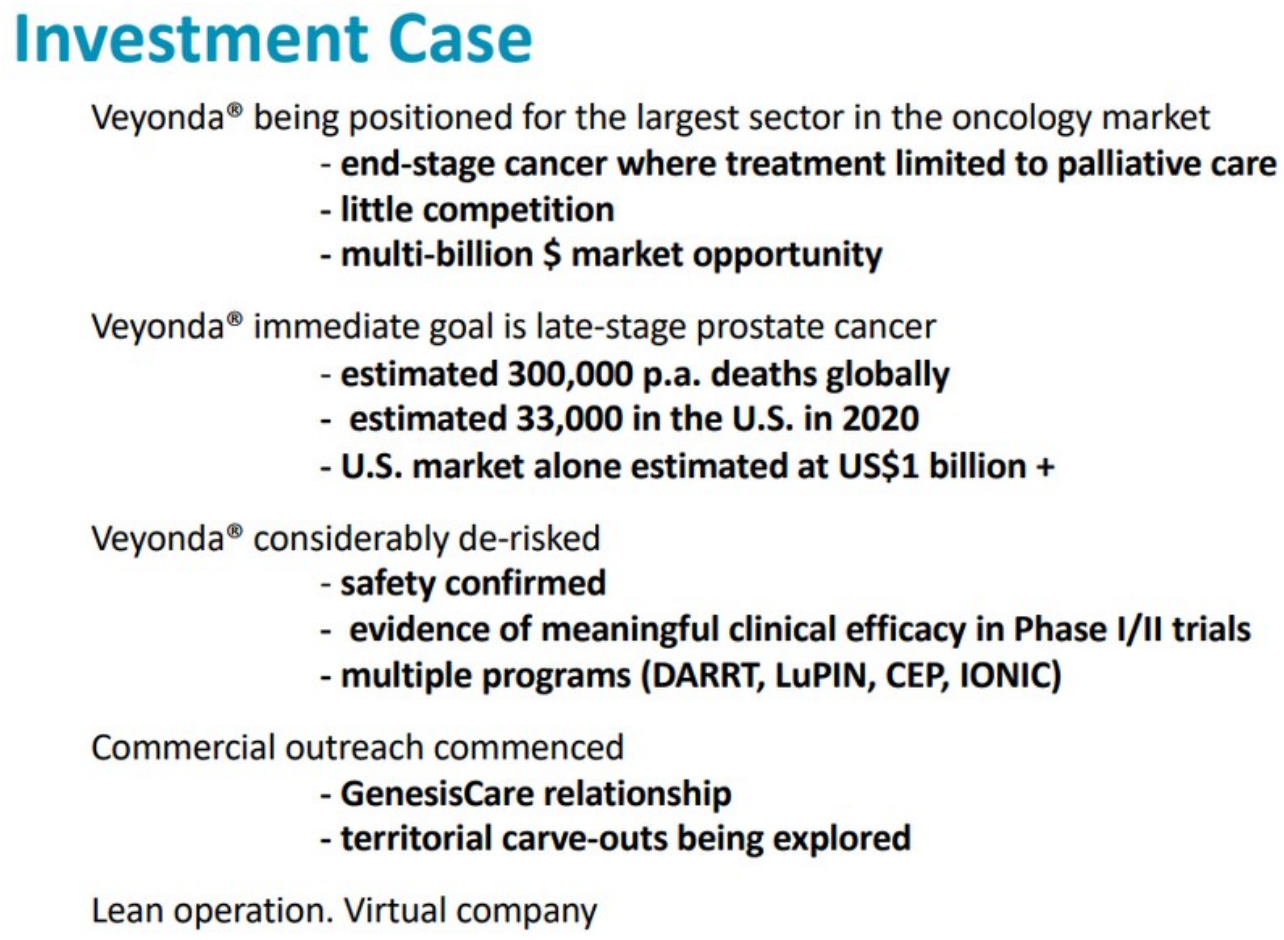
Noxopharm is a clinical-stage Australian drug development company with its primary focus being the development of Veyonda®.

The submission is based on a response to a package submitted to the FDA summarising the rationale for conducting a clinical trial with an inhibitor of cGAS-STING signaling.

The urgency of the situation means that if the pre-IND is evaluated positively by the FDA, it can be converted into a fully expedited IND approval.

The conversion of a pre-IND into a full IND is a new option offered to high priority COVID-submissions, significantly reducing the time and complexity of the FDA review process.

Veyonda® has a mechanism of action that Noxopharm believes marks it as a prospective treatment of septic shock in COVID-19 patients, a condition associated with inflammatory and clotting problems and believed to be contributing to multi-organ failure and death in COVID-19 patients.



Idronoxil a potent inhibitor of cGAS-STING signalling pathway

Pre-clinical research conducted by the Hudson Institute of Medical Research has shown that one of the anti-cancer mechanisms of action of idronoxil (the active ingredient in Veyonda®) is potent inhibition of the cGAS-STING signalling pathway.

The cGAS-STING signalling pathway is responsible for alerting the body's immune system to the presence of an invading virus by triggering the production of cytokines.

This pathway is critically important in generating an immune response that contributes to the great majority of COVID-19 patients recovering uneventfully.

However, in a small proportion of patients who develop breathing problems leading to low oxygen levels, tissue damage in major organs triggers a second and excessive wave of cGAS-STING signalling, resulting in a so-called 'cytokine storm', amplifying existing tissue damage and inducing blood clotting problems.

A number of COVID-19 clinical trials are being conducted with drugs inhibiting individual components of the 'cytokine storm' such as IL-6 and TNF -alpha.

The basis of the Noxopharm submission to the FDA is that by inhibiting the cGAS-STING signalling pathway, Veyonda® offers a special opportunity to block a broader range of cytokines at their source, potentially preventing it altogether or reducing the severity of septic shock and the number of patients dying from it.

The proposed study involves dose-response, dose confirmation and dose expansion with the latter involving a comparison of Veyonda® with current standard of care treatment.