Noxopharm Investigating Idronoxil's Potential in COVID-19 Treatment

Australian oncology drug development company Noxopharm (<u>ASX:NOX</u>), along with the Hudson Institute of Medical Research in Melbourne, has identified antiinflammatory properties of idronoxil, consistent with reducing a 'cytokine storm' which is believed responsible for many COVID-19 deaths. Idronoxil is a first-inclass inhibitor of sphingosine-1-phosphate (S1P) via inhibition of ENOX2. It is the active compound in Veyonda[®], Noxopharm's lead cancer drug candidate.

After the announcement, NOX's stock surged by ~93 per cent to 0.270 on 1^{st} April 2020.

The Company will be continuing to focus on its <u>Veyonda[®]</u> cancer trial clinical programs while assessing the potential ability of idronoxil to help reduce the COVID-19 associated mortality rate.

Noxopharm is a clinical stage drug developer engaged in commercialisation of dual cytotoxic/immuno-oncology drug Veyonda[®] - a suppository dosage form of idronoxil ,for late stage <u>prostate cancer</u>. The Company is planning to enter in to the multi-billion dollar oncology market opportunity, where end- treatment is limited to palliative care, and there are few current alternative treatments.

Noxopharm is running various cancer treatment programs, including <u>DARRT</u> (Direct and Abscopal Response to Radiation Therapy), LuPIN (Lutetium-PSMA in Combination with <u>NOX66</u>), CEP (Chemo-Enhancement Program) and increasingly, Veyonda[®] is found to have its safety confirmed with evidence of signs of meaningful clinical efficacy in Phase I/II trials.

<u>Evaluating Idronoxil for COVID-19 Treatment</u>

Noxopharm has proposed to review the use of idronoxil in patients at risk of developing multi-organ failure and acute respiratory distress syndrome (ARDS) associated with COVID-19 infection.

The proposal is to use Veyonda in patients who are showing early signs of organ damage with elevated blood levels of numerous cytokines and who are at the beginning of a potential cytokine storm response. The Company has planned to select patients based onsymptoms of early multi-organ failure and/or elevated blood levels of specific cytokines like interleukin-6 (IL-6).

Noxopharm's goal is to diminish the mortality rates and the pressure on limited ICU facilities by blocking the worsening of ARDS and multi-organ failure and the progression of the cytokine storm.

<u>Why Idronoxil?</u>

The Hudson Institute and Noxopharm have been collaborating for the last one year to better grasp the actions of idronoxil on the immune system.

The Hudson Institute discovered in their pre-clinical models that idronoxil has two unique features:

- It seems to inhibit the production of cytokines like IL-6, possibly inhibiting their upstream signalling pathways resulting in a broader effect, in comparison to the monoclonal antibodies that simply block the function of a single specific cytokine.
- A broader set of cytokines are inhibited (beyond IL-6 and TNF-a), all incriminated in the damaging effects of the cytokine storm.

The pre-clinical models indicate the ability of idronoxil to treat patients with early-stage organ failure and prevent the need for intensive care units (ICUs).

Both the Hudson Institute and Noxopharm have acknowledged that themechanism of action and theset of cytokines impeded by idronoxil has some novel aspects, and are potentially important in treating a cytokine storm as it applies to septic shock, believed to be an untreatable condition resulting in several deaths worldwide.

The inventors of these findings are Dr Michael Gantier, Dr Graham Kelly and Dr Olivier Laczka.

Noxopharm is also planning to publish these findings in the scientific literature at the earliest opportunity.

These outcomes are also the subject of a provisional <u>patent</u> application filed by Noxopharm with the Australian Patent Office this week and focused on the use of idronoxil for early-stage organ damage connected with inflammation triggered by bacterial or viral infection to reduce organ damage and avert sepsis and ARDS.

Noxopharm and the Hudson Institute believe that idronoxil's broader cytokine coverage has the potential to provide a more effective treatment against cytokine cascades in COVID-19 patients.

Both the parties intend to develop an idronoxil derivative as an effective therapy for the septic shock treatment in general. Meanwhile, considering the emerging global emergency with the COVID-19 pandemic, the Company has planned to make idronoxil available as a potential cytokine storm inhibitor for immediate clinical use.

Noxopharm will be seeking non-dilutive support in both the domestic and international markets for the proposed clinical study.

<u>Noxopharm's Next Moves</u>

Noxopharm has begun discussions with various governmental agencies to gain the required funding subsequent to thelodgement of provisional patent.

Noxopharm has also begun the process of reaching out to clinicians in different countries in order to recruit potential clinical sites. The Company has also planned to work with its regulatory affairs advisors on the actions needed to obtain regulatory approval to undertake a clinical trial.

With idronoxil already in the clinic, Noxopharm is well-positioned to start clinical testing as early as it receives the required financing and regulatory consents.

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