Noxopharm says study advancing after clinical review

January 14, 2021

Noxopharm (ASX:NOX) has announced that the latest formal review by the NOXCOVID-1 Safety Steering Committee has cleared it to advance to the fifth and final dosage cohort.

The independent committee voted unanimously to move to the 1800 mg dose after they reviewed the safety profile of Veyonda in 12 patients from cohorts three and four (involving 800 and 1200 mg Veyonda respectively).

The company said this as a highly encouraging outcome given the advanced nature of COVID-19 disease in these study patients, in particular suffering serious lung dysfunction.

It said it will be reporting formally on efficacy in due course, with the overall objective being to use Veyonda to block the cytokine release syndrome (so-called 'cytokine storm') that leads to patients requiring intensive care, and is a primary cause of the multi-organ damage responsible for much of the long-term disability and death in COVID-19 patients.

According to Noxopharm CEO Dr Graham Kelly, "Patients we are treating are at the stage of COVID-19 disease generally associated with high rates of deteriorating lung function requiring intensive care. While early days, the progress of the trial is serving to boost our confidence that Veyonda is capable of meeting its primary objective of blocking the cytokine release syndrome causing that rapid deterioration, and doing so in a well-tolerated and minimally-intrusive way."

Dr Kelly continued, "Noxopharm sees a commitment to the NOXCOVID trial as adding considerable commercial value to Veyonda, apart from obvious humanitarian reasons. With an estimated 11 million deaths each year from septic shock, the need to block cytokine release syndrome effectively and safely goes well beyond the current pandemic with its estimated approximately 2 million deaths to date.

"While Veyonda remains the Company's current spearhead drug in the septic shock field with a potential major role to play in the pandemic, our subsidiary Pharmorage in collaboration with Hudson Institute of Medical Research and the Australian National University is underway in developing a drug purpose-built for septic shock across all situations."

Members invited to Industry and state government updates

January 14, 2021

Completing the 'Update online roadshow' AusBiotech members from Queensland and Western Australian are invited to hear the latest information from their State Government representative at AusBiotech's Industry Update, which aims to grow and support the biotech industry.

Facilitated by Michelle Burke, Chair, AusBiotech, Members are invited to join Mark Tierney, Executive Director, Industry Development – QLD Department of State Development, Tourism and Innovation on 20 January; and Dr Debra Cousins, Executive Director, WA Department of Jobs, Tourism, Science and Innovation on 10 February, for a live industry update.

Lorraine Chiroiu, CEO, AusBiotech will discuss national policy advocacy for the sector during these tailored events.

These events are delivered as part of AusBiotech's virtual Industry Update roadshow and are limited to AusBiotech members only, which includes SMEs, multinational organisations, support services, universities, and research institutes.

The Victorian Industry Update, delivered late last year and available to members in the BiotechTalks Library for a limited time, included an update on the State Budget that was announced a week prior to the event. Chris Barrett, CEO, Invest Victoria, and Paul Stagg, Director, Trade, Global Victoria, Department of Jobs, Precincts and Regions (DJPR), joined Michelle Burke and Lorraine Chiroiu.

Initiatives discussed included:

- Significant investment through the newly announced $2bn Breakthrough Victoria Fund, to drive investment in research innovation and the next great breakthroughs over the next 10 years, including how the fund is being set up, and next steps;
- To better access and engage with international markets, the e-commerce programme is broadening, including promotional activities, market and sector insights, and creating digital collateral;
- Advocacy for VIC interests for the Commonwealth International Freight assistance programme that connects exporters with key markets and is in place until June 2021;
- A new $15.7m Export Recovery Package: to establish new export channels, adapt existing export strategies, and remain connected to key markets through key activities, e.g. virtual trade missions.
- One-off grants of up to $50,000 available through VIC's Global Gateway Programme, for companies to pivot to stabilise their export activity or adapt their export strategy to mitigate barriers caused by COVID-19. Grants are expected to subsidise 80 per cent of project costs;
- Update on the new International Investment Strategy, launched in March 2020, that covers digital technology, advanced manufacturing, health and life sciences, and agri-food;
- Highlighting the new four pillars of the 'Jobs Plan', that aims to create 200,000 jobs by 2022 and 400,000 jobs by 2025;
- $20m to champion, develop and identify new opportunities for VIC's medtech manufacturing and innovation sector, and $50m to focus on manufacturing and industry development, including sovereign manufacturing and industry supply capability in Victoria;
- $210m to support research organisations and institutes, including the Australian Institute for Infectious Disease;
- Funds to address access to capital challenges;
- Supporting regenerative medicine as emerging technologies, and how a roadmap and sustainable body will drive it forward for the future of Australia; and,
- What the latest significant RDTI announcements mean to Australian biotech companies.

Read more about the upcoming QLD/WA webcasts and their speakers, and register here.

Already have a burning question or an issue you want an update on from Lorraine or your State Government representative? Pre-submitted questions will take precedence so ask AusBiotech now; as many as possible will be covered in the presentation and Q&A.

Clinical trial finds vitamin D does not ward off colds and flu

January 14, 2021

A QIMR Berghofer-led randomised controlled trial of vitamin D supplements has found they do not protect most people from developing colds, cases of flu and other acute respiratory infections.

The trial is the largest of its kind to study the relationship between vitamin D and respiratory infection. It did show the supplements may shorten the length of infection, slightly, and help ease the severity of those illnesses.

The researchers analysed self-reported health data from 16,000 Australians aged between 60 and 84.

The participants were given either a capsule of 60,000 international units of vitamin D, or a placebo, every month for up to five years. They completed annual health reports and some recorded their respiratory symptoms in diaries for eight weeks over the winter months.

Lead researcher and head of QIMR Berghofer's Cancer Aetiology and Prevention group, Professor Rachel Neale, said participants who received vitamin D supplements reported they had cold and flu symptoms for slightly less time than participants who did not take the vitamin. They also had severe symptoms for less time and needed less medication to manage their symptoms.

"Our clinical trial showed that people who took vitamin D supplements were infected with colds and flus at the same rate as those who were given placebos. Those who got the supplements did, however on average, report a small reduction in the number of days they experienced symptoms (on average about half a day)," said Professor Neale.

"The findings suggest that vitamin D might give the immune system a little boost, but supplementing the general population with vitamin D is unlikely to protect people from getting sick in the first place and won't markedly improve the speed of recovery.

"It is important to note that this trial was conducted on Australians and most of the participants were not vitamin D deficient to start with. It is possible that a greater protective effect would be seen in countries where a high proportion of the population is vitamin D deficient.

"This study suggests that taking supplements will not have significant benefits for warding off colds and flus in people who are not vitamin D deficient."

Data from the 2011-12 National Health Survey suggest up to one-in-four Australian adults may have low vitamin D.

Data also shows most Australians experience a respiratory tract infection, such as the common cold or influenza, at least once per year. Infection rates are generally highest during winter months when people's vitamin D levels are lowest because of reduced ultraviolet radiation and more time spent indoors.

Professor Neale said the trial results are timely as people around the globe try to understand how best to improve their immunity in the face of the COVID-19 pandemic.

"The studies that have been published do suggest that having higher vitamin D levels may reduce the risk and severity of COVID-19, but these studies have had fairly serious limitations, so the results are not reliable," she said.

The researchers are now planning to use the data gathered during the trial to examine the effects of vitamin D on other health problems including depression, cancer and heart disease.

The study results have been published in the scientific journal *The Lancet Diabetes and Endocrinology*.

The D-Health Trial was funded by the National Health and Medical Research Council of Australia.