FDA allows Veyonda pre-IND Submission for COVID-19

May 21, 2020

Noxopharm (ASX:NOX) has lodged a pre-Investigational New Drug (pre-IND) submission with the US FDA for a clinical trial of its Veyonda in patients with COVID-19 infection.

The company said 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 signalling.

It said, based on the current COVID-19 pandemic, a pre-IND can be converted into a fully expedited IND approval for relevant therapies. This reduces the time and complexity of the FDA review process.

Veyonda has a mechanism of action Noxopharm believes marks it as a prospective treatment of septic shock in COVID-19 patients.

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 important to 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.

Consultation: Enhancing transparency measures for prescription medicines

May 21, 2020

The Australian Government has given approval to proceed with the implementation of enhanced transparency measures for prescription medicines, in response to public demand for more information on prescription medicines that are under evaluation.

AusBiotech is seeking member feedback on the two proposed implementation options, including the preferred notification option, predicted impacts (financial and non-financial), and any changes that would minimise the burden on industry.

The Australian Government is proposing to increase transparency for applications under evaluation in a way that balances the availability of information to the public while recognising that this information could have commercial value to the applicant.

Consumers, their carers and families, together with healthcare professionals, have said they are frustrated in not being able to know whether new treatments are likely to be available in Australia as they are not aware that an application has been made to the TGA.

Measure one: Early publication of major innovator medicine applications

Information on the potential availability of new medicines or new uses for medicines is considered to be of the

greatest value to consumers and healthcare professionals. This measure will introduce earlier publication of major innovator prescription medicines that have been accepted for evaluation under section 25 of the Act.

This measure could commence from June 2020. No additional actions are required by the applicant for registration of the medicine. The TGA will publish information within one month of the date that an affected application has passed the preliminary assessment.

Measure two: Earlier notification of generic medicine applications to the innovator

It is expected that there would be less public interest in the notifications of generic prescription medicine evaluations as many follow-on from previously-registered generic medicines that are already on the market.

This measure will introduce earlier notification of generic medicine applications to the innovator. Implementation is planned from early 2021. This is intended to address the flaw (whether there is notification prior to registration of the generic is at the sole discretion of the generic) in the existing notification scheme which has caused the significant cost to the generic, the innovator and the community as manifested in the expensive patent dispute litigation.

There are two options for implementing an early notification scheme for new generic medicines:

1. Option one requires early notification in addition to the existing scheme, only where a patent has not expired.
   The purpose of this option is to remove the assessment of whether the marketing of the generic (should its application for registration be approved) would infringe a valid claim of a patent from being at the sole discretion of the applicant. The obligation on the applicant is reduced to apply only in circumstances in which it has a reasonable belief about the existence of a valid patent. In effect, whether the marketing would so infringe the patent would be for the applicant and the patentee to resolve.
2. Option two requires early notification regardless of belief of the existence of a patent. This option would, in addition to moving the current certification or notification requirements to the earlier point in the process also require the applicant to provide notification to the innovator where the applicant determines that a valid patent is not infringed.

In February 2019, the TGA released a public consultation paper on *Whether the TGA should publish that a prescription medicine is under evaluation*. Read previous responses and the implementation's consultation document here.

AusBiotech asks members email or call (03 9828 1455) Juliana Potulic, Policy and Programmes Manager, AusBiotech, with your views and comments by Tuesday 2 June 2020.

OneVentures appoints new executives to healthcare team

May 21, 2020

Australian venture capital firm OneVentures has announced the appointment of John Westwater and Kelly Constable to its healthcare team.

OneVentures said Dr Westwater and Ms Constable will help drive growth across its healthcare sector portfolio and provide insight and access to their extensive networks in the healthcare ecosystem in Australia, the US and Europe.

OneVentures launched its $170M Healthcare Fund III (Fund) in December 2016. It is a licensee of the Australian Government Biomedical Translation Fund (BTF). The Fund is investing $10-20 million in companies commercialising medical devices, drugs in clinical development or diagnostics.

It has invested in five healthcare sector companies including Kira Biotech, developing novel antibody treatment to induce immune tolerance for autoimmune and other disorders, Blade Therapeutics, a company developing small molecule drugs for the treatment of fibrosis, and BiVACOR, creators of the first Total Artificial Heart for replacement of a patient's failing heart.

According to OneVentures managing partner, Dr Paul Kelly, "We are excited to have John and Kelly bring their experience and expertise to OneVentures. Biomedical and Healthcare innovation is moving at a rapid pace and both bring their respective and specific backgrounds to OneVentures as we continue to focus on commercialising Australia's exceptional medical innovations globally, especially as technology and healthcare innovation are integrating at a dramatic rate."

Dr Westwater brings almost 20 years' global life science experience across operational, venture capital and investment banking roles, having most recently held the role of CFO of Elastagen. He was previously a principal at Nomura Phase4 Ventures in London.

Kelly Constable is also serving as OneVentures director on the board of Prota Therapeutics, and member of the Advisory Committee for the Fund, focusing on internationalising existing portfolio companies and identifying new opportunities. She currently holds the position of co-founder and CEO of AULUS Partners and is the chief strategy officer for Omico, a precision oncology clinical trials platform.

Dr Westwater said, "I am delighted to join the OneVentures healthcare team and in particular the opportunity to support emerging life science companies on their journeys to becoming Australia's next wave of success stories."

Ms Constable said, "I have great respect for the OneVentures approach to healthcare investing in Australia and the vital role this plays in accelerating life sciences technologies for patients. There is no doubt healthcare investing will be an increasingly important national endeavour for Australia in the post-Covid19 world. I look forward to contributing to OneVentures' portfolio architecture and execution and supporting Australia's entrepreneurs."