Questions & Answers on licence application DIR 184 – Clinical trial with genetically modified human adenovirus COVID-19 vaccine

What does this licence allow?

Avance Clinical Pty Ltd is conducting a clinical trial of a COVID-19 vaccine, in Australia. COVID-19 is caused by a virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). People with COVID-19 can exhibit a wide range of symptoms, which vary from mild to severe illness or death in some cases. The purpose of this clinical trial is to assess intranasal administration of a GM vaccine for COVID-19, which is different to the intramuscular administration of other COVID-19 vaccines currently in use. The GM vaccine will be manufactured overseas and imported directly to clinical trial sites in Australia. Up to 1000 healthy participants will be administered with the GM vaccine at clinical trial sites and hospitals in Australia.

How has the Avance Clinical Pty Ltd COVID-19 vaccine been made and how does it work?

The vaccine uses an adenovirus vector that has been modified to contain a gene to make the SARS-CoV-2 spike protein. Once vaccinated, people produce antibodies against the spike protein and this helps to protect against COVID-19. The adenovirus vector cannot replicate, spread or cause disease.

What other regulatory processes apply to this trial?

Clinical trials must be conducted in accordance with requirements of the Therapeutic Goods Administration (TGA), which address the safety of trial participants. Before commencing, the trials will require ethics approval, and must be conducted in accordance with the *Guidelines for Good Clinical Practice*. Import of the GM human adenovirus treatment will also require approval from the Department of Agriculture, Water and the Environment.

Has the GM treatment been previously tested or used?

This is a first in human clinical trial using intranasal administration. A licence to conduct a clinical trial using the intramuscular route of administration has been previously approved by the Regulator.

Preclinical studies have been undertaken in animal models which showed good efficacy and no major adverse reactions.

What controls are imposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that the clinical trial poses negligible risks to people or the environment. However, as this is a clinical trial under limited and controlled conditions, a number of licence conditions have been imposed to restrict when and where the trial can take place, limit the size of the trial, and restrict the spread and persistence of the GM vaccine. For example, there are conditions relating to preparation and administration of the GM vaccine, secure transport and storage of the GM vaccine and appropriate waste disposal. Full details of these control measures are included in the licence.

Want more information?

A number of documents relating to this decision are available on the DIR 184 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

The Office of the Gene Technology Regulator

OGTR Website

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