Questions & Answers on licence DIR 140

Clinical trial of a genetically modified (GM) virus for liver cancer treatment

What does this licence allow?

Clinical Network Services Pty Ltd (CNS) has received an approval under *the Gene Technology Act 2000* to conduct a Phase 3 clinical trial of a GM virus for treatment of patients with advanced liver cancer. The trial will take place in hospitals throughout Australia. Up to 75 cancer patients may be enrolled in the trial, which is expected to be completed within one year.

What other regulatory approvals 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, and the National Statement on the Ethical Conduct in Research Involving Humans. The trial will require approval from, and oversight by, the Human Research Ethics Committee at each clinical site. As the GM virus will be imported, an import permit must be obtained from the Department of Agriculture and Water Resources.

What is the purpose of the proposed clinical trial?

The purpose of the trial is to assess the effectiveness and safety of the GM virus as a treatment for Hepatocellular Carcinoma (HCC), a common type of liver cancer, when provided in conjunction with a standard treatment. The proposed study would form part of an international multi-centre Phase 3 clinical trial involving 600 patients in total.

What is the GM virus and how was it made?

This is a genetically modified vaccinia virus. Vaccinia viruses were used world-wide as vaccines to protect against smallpox infection. The virus has been genetically modified to increase its selectivity for cancer cells and reduce its ability to grow in normal tissue by disrupting a gene important for viral reproduction. In addition, it contains a gene for a human protein that stimulates certain types of immune cells, helping to destroy tumours throughout the body. It also has a 'marker gene' which allows quick and easy detection in blood and tissue samples collected from trial participants.

How will patients be treated with the GM virus?

The GM virus will be administered to adult volunteers with advanced HCC. It will be injected directly into tumours by trained medical staff in hospitals that offer specialised cancer treatment services. A series of three treatments will be administered to each participant over a four week period. Treatment will be followed by a standard treatment for HCC.

Has this GM virus been previously tested?

This treatment has been or is currently being evaluated in thirteen clinical trials in multiple countries, including the USA, Canada, France, Germany, The Republic of Korea, China and Taiwan. Over 300 patients have been treated in these trials.

What controls have been imposed for this trial?

The Risk Assessment and Risk Management Plan (RARMP) for this application concluded that the trial poses negligible to low risks to people and the environment. Licence conditions have been imposed to manage the risk, limit the scale and scope of the clinical trial, and restrict the spread and persistence of the GM virus. Control measures include administration of the GM virus by trained medical staff only, exclusion of individuals at risk of adverse effects from the trial, educating trial volunteers about measures to prevent transmission of the GM virus, and appropriate disposal of all trial waste. Full details of these licence conditions are set out in the RARMP.

Want more information?

Several documents relating to this decision are available on the DIR 140 page of the OGTR website. These documents include the finalised RARMP, a summary of the RARMP and the licence.

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