24 October 2024

# Summary of Licence Application DIR 208

Novotech (Australia) Pty Ltd (Novotech) has made an application under the *Gene Technology Act 2000* (the Act) to conduct a Phase 1 clinical trial using genetically modified organisms (GMOs).

| | |
|---|---|
| ***Project Title*** | Clinical trial of genetically modified (GM) Vaccinia virus for the treatment of solid tumours |
| ***Parent organism*** | *Vaccinia virus* (VACV) |
| ***Genetic modifications*** | |
| Introduced/Deleted genes | Introduced genes[1]:<br>• Three separate genes related to immune function of human origin, which enhance anti-tumour immune responses.<br>Deleted genes[1]:<br>• The deletion of three VACV genes, which improves the efficacy and safety of the GMO. |
| ***Principal purpose*** | The proposed trial is a Phase 1 study designed to evaluate the safety and efficacy of the GM VACV. |
| ***Previous clinical trials*** | This is a first in human clinical trial using this GMO. |
| ***Proposed limits*** | |
| Proposed location/s | The proposed trial would be conducted at a number of hospitals and clinics across Australia. The exact sites are yet to be identified. |
| Proposed number of participants | Up to 40 clinical trial participants in Australia |
| Proposed period of release | 5 years |
| Proposed controls | • Transport and store the GMO according to *Transport, Storage and Disposal Guidelines* appropriate for PC2 GMOs<br>• Require staff handling the GMO to be trained and to use personal protective equipment<br>• Pregnant staff are excluded from handling the GMO<br>• All waste materials generated from the trial will be appropriately contained and disposed of as per clinical waste. |

**The application**

The applicant proposes to administer the GM VACV to patients with advanced or refractory solid tumours which have not responded to standard therapies. This GM VACV has been designed to preferentially multiply in and kill cancer cells. Up to 40 patients in Australia would receive a single intravenous dose of the GM VACV and be observed over a period of 28 days, with the aim to evaluate the treatment's safety and

[1] Confidential Commercial Information: Some details about the inserted and deleted genes in GM Vaccinia have been declared as Confidential Commercial Information under section 185 of the Act. This information will be made available to the prescribed experts and agencies that will be consulted on this application. CCI is not available to the public.

efficacy. The proposed clinical trial must meet the Therapeutic Goods Administration (TGA) requirements and would need approval from a registered Human Research Ethics Committee prior to commencement.

The application is for limited and controlled release under section 50A of the Act, as the Regulator was satisfied that its principal purpose is to enable the applicant to conduct the trial, and the proposed limits and controls are such that consultation with prescribed experts, agencies and jurisdictions is not required at this stage.

**Next steps**

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

The Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application including the proposed limits and controls in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed clinical trial.

At this stage, the consultation RARMP is expected to be released for comment in **December 2024**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the OGTR website when they are released.

**Other information available from the OGTR website:**

- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below, if you

- would like a copy of the application. Please include the identifier DIR 208.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

**The Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra ACT 2601**
**Telephone: 1800 181 030**
**Email: ogtr@health.gov.au**