Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

17 May 2023

Summary of Licence Application DIR 197

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

Project Title	Clinical trial of genetically modified *Lactobacillus brevis* for treatment of inflammatory bowel disease
Parent organism	*Lactobacillus brevis*
Genetic modifications	
Introduced gene	Introduced gene encoding human vasoactive intestinal peptide (VIP), which has anti-inflammatory effects
Principal purpose	(a) To assess the safety of single and multiple ascending doses of the GMO in healthy clinical trial participants, and (b) To assess the safety and efficacy of multiple doses of the GMO in clinical trial participants with ulcerative colitis
Previous clinical trials	None
Proposed limits	
Proposed release size	Up to 60 clinical trial participants in Australia
Proposed period of release	7 years

Proposed controls include measures to:

- Import the GMO in a form that is double-packaged and ready for administration
- Track GMO doses that have been dispensed to clinical trial participants for self-administration at home and destroy any GMO doses that remain unused at the end of the trial
- Issue spill kits to trial participants to clean up any spill of GMO that occurs at home.

The application

The applicant proposes to orally administer the live GM bacteria to healthy adults and to adults with active ulcerative colitis. The GMO treatment is designed to reduce inflammation of the gastrointestinal tract. The treatment duration would range from a single dose to daily doses over a period of 8 weeks. The proposed clinical trial must meet 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 clinical 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 **July 2023**.

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 197.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

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