



Australian Government

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

NOTIFICATION OF APPLICATION

Receipt of licence application from Novotech Australia Pty Ltd for clinical trial of genetically modified human adenovirus for treatment of melanoma

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 213) from Novotech Australia Pty Ltd to conduct a clinical trial of genetically modified (GM) human adenovirus for treatment of melanoma. A summary of the application is posted on our [website](#) (search for [DIR 213](#)).

The clinical trial is proposed to take place at hospitals and clinics within Australia over a period of 3 years. Up to 30 patients in Australia would receive up to 7 doses of the GM treatment over a period of 3 months, with the aim to evaluate the treatment's safety and efficacy.

The OGTR is preparing a Risk Assessment and Risk Management Plan for the application. This is expected to be released for public comment and advice from experts, agencies and authorities in **early March 2025**. There will be at least 30 days for submission of comments.

If you have any questions or would like to receive a copy of the application or the summary, please contact the OGTR and quote the reference number DIR 213.

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