



Australian Government

Department of Health, Disability and Ageing

Office of the Gene Technology Regulator

NOTIFICATION OF APPLICATION

***Receipt of licence application from Krystal Biotech Pty Ltd for the commercial supply of beremagene
geperpavec (B-VEC) for the treatment of wounds in patients with dystrophic epidermolysis bullosa
(DEB)***

The Office of the Gene Technology Regulator (OGTR) has received a licence application (DIR 229) from Krystal Biotech Pty Ltd for the import, transport, storage, and disposal of a genetically modified (GM) therapeutic for treatment of wounds in patients with DEB in Australia.

The applicant proposes to supply the GM therapeutic for administration to patients with DEB. The proposed commercial supply must meet Therapeutic Goods Administration requirements, and the proposed import would need approval from the Department of Agriculture, Fisheries and Forestry (Biosecurity) prior to commencement.

The OGTR is preparing a Risk Assessment and Risk Management Plan for the application. The RARMP will be prepared taking into account advice received from a broad range of experts, agencies and authorities, and relevant local councils, as specified in the *Gene Technology Act 2000*. This is expected to be released for public comment and advice from experts, agencies and authorities in **March 2027**. There will be at least 60 days for submission of comments.

A summary of the application and a Questions and Answers documents are posted on our [website](#) (search for DIR 229). 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 229.

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