

## **Questions & Answers on licence application DIR 229 – Commercial supply of beremagene geperpavec (B-VEC) for the treatment of wounds in patients with dystrophic epidermolysis bullosa (DEB).**

### **What is this application for?**

Krystal Biotech Pty Ltd has submitted an application for the commercial supply of a topical gene therapy to treat the wounds of patients with DEB. The applicant is seeking approval for the import, transport, storage, and disposal of the genetically modified (GM) therapeutic for treatment of patients in Australia. The use of the GM therapeutic in patients will also require a separate approval by the Therapeutics Goods Administration, which considers safety and efficacy of the therapeutic in people receiving the treatment as part of their approval process. A permit from the Department of Agriculture, Fisheries and Forestry will also be required for import of the GM therapeutic into Australia.

### **How has the GM therapeutic been made?**

The GM therapeutic has been generated by modifying Herpes Simplex Virus-1 (HSV-1), removing DNA sequences necessary for viral replication to improve patient safety. A gene encoding a human collagen protein, a critical component of skin tissue, has been introduced to treat skin lesions in patients with DEB. The GMO is designed to deliver collagen protein to skin cells at wound sites in DEB patients enabling the cells to produce collagen to support wound healing.

### **What is the purpose of the commercial supply?**

The applicant proposes to supply the GM therapeutic to a TGA-licence pharmaceutical facility for the distribution and administration to patients for the treatment of DEB.

### **What is the process for considering this application?**

The licence application will be subject to a comprehensive and science-based risk analysis. The analysis will consider whether there are any potential risks to human health and safety or the environment from the proposed GM treatment. The OGTR will consult with a wide range of experts and the public prior to finalising the risk analysis.

### **When can I comment on this application?**

A consultation RARMP for this application is expected to be released for public comment in March 2027. We will notify subscribers to [OGTR News](#) of the consultation and advertise it in newspapers and on our [website](#). The consultation will be open for written submissions for about 2 months.

While comment is not being sought from the public at this stage, you can obtain a copy of the full application by contacting the OGTR. Please quote the application number DIR-229 in any communications with us about this application. A summary of the application is available on the [OGTR website](#).