Australian Government
Department of Health
Office of the Gene Technology Regulator

7 July 2021

**Notification of decision on application DIR 181 from Novotech (Australia) Pty Limited – Clinical trial of a genetically modified Herpes virus for the treatment of cystic fibrosis**

The Regulator has issued licence DIR 181 to Novotech (Australia) Pty Limited, authorising the clinical trial of a genetically modified (GM) Herpes virus for the treatment of cystic fibrosis.

The Risk Assessment and Risk Management Plan (RARMP) and the licence were finalised taking into account input received during consultation with the public, State and Territory Governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee and local councils. The Regulator thanks submitters for their contributions.

Submissions are summarised in Appendix A of the RARMP, together with information about how the issues raised relating to risks to human health and safety or the environment were considered in preparing and finalising the RARMP. To manage these risks, licence conditions have been imposed requiring that trial participants be seronegative for HSV-1, be monitored over the course of the trial for primary HSV-1 infection and offered anti-viral medication if they acquire an infection. Effective protection of clinical trial staff from aerosolised GMO is also required. The licence also limits the number of trial participants, the types of facility where the trial may be conducted, and the duration of the trial. A range of additional controls are imposed to minimise the potential for exposure of people other than trial participants, and susceptible animals, to the GMO.

The finalised RARMP, a summary of the RARMP, the licence and Questions and Answers about this decision can be obtained online from the DIR 181 page of the Office of the Gene Technology Regulator's (OGTR) website or requested via the contacts detailed below.

**Office of the Gene Technology Regulator**
**MDP 54 GPO Box 9848 CANBERRA ACT 2601 Tel: 1800 181 030 E-mail: ogtr@health.gov.au**
**OGTR website**