

Questions & Answers on licence DIR 223 – Clinical trials of a genetically modified adenovirus for the treatment of bladder cancer

What does this licence allow?

Ferring Pharmaceuticals Pty Ltd (Ferring) has been issued a licence to conduct clinical trials, under limited and controlled conditions, of a genetically modified (GM) adenovirus for the treatment of bladder cancer.

The GM treatment has been designed to increase anticancer activity via direct cytotoxic effects on tumours and immunostimulatory effects to kill cancer cells. The GM adenovirus would be manufactured overseas and imported into Australia. Up to 25 patients with bladder cancer are permitted to be treated with the GM adenovirus at clinical trial sites and hospitals in Australia, over a period of 5 years.

How has the GM adenovirus been modified?

The GM treatment is based on human *adenovirus*, which has been genetically modified by removing DNA sequences to make it safe for patients and introducing a gene to express a protein with anti-tumour effects. It can enter urothelial and tumour cells and produce the protein with anti-tumour effects within the infected cells.

What is the purpose of the trials?

The aim of the clinical trials is to gather data to assess the effectiveness of the GM treatment in patients with non-muscle invasive bladder cancer.

What other regulatory processes apply to these trials?

Clinical trials must be conducted in accordance with requirements of the Therapeutic Goods Administration, which address the safety of trial participants. Before commencing, the trials would require ethics approval and must be conducted in accordance with the Guidelines for Good Clinical Practice. Import of the GM treatment will also require approval from the Department of Agriculture, Forestry and Fisheries.

What controls are imposed for this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the clinical trial poses negligible risks to people or the environment. However, as this is a clinical trial, Ferring must comply with a range of licence conditions. These conditions limit the number of trial participants, limit the location of the clinical trial to hospitals and clinical trial sites, limit the duration of the trial, and specify a range of controls to minimise the potential for the GM treatment to spread in the environment. For example, there are conditions relating to administration of the GM treatment and appropriate waste disposal. Full details of these control measures are in the licence.

Want more information?

A number of documents relating to this decision are available on the [DIR 223](#) page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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