**GE Free New Zealand**

**PO Box 13402, Wellington, Aotearoa | NZ**
**www.gefree.org.nz**

8 December 2024

Re: APP203750 Chimaeric Antigen Receptor T-cells and
Re: APP203530 genetically modified live-attenuated vaccinia virus (Pexa-Vec)

Tēnā koe Dr Freeth,

We have two requests for documents, under the OIA, to our questions relating to APP203750 and APP203530.

**Re: APP203750 Chimaeric Antigen Receptor T-cells**

1. When did the New Zealand sponsor notify the EPA of the start of APP203750 Phase 1 clinical trial?
2. What were the outcomes on the safety and efficacy of the clinical trial?
3. How many participants were involved in the APP203750 trial?
4. Has a written notification of the conclusion of the trails been received?
5. Has APP203750 been lawfully approved for use under the Medicines Act 1981. in New Zealand?
6. Please could we have the outcome of the trial,
    a. any adverse effects?
    b. Any deaths?
    c. the level of drop outs?
    d. Any transmission events documented?

**Re: APP203530 genetically modified live-attenuated vaccinia virus (Pexa-Vec)**

We note that in 2018 you approved the release of the Pexa-Vec (pexastimogene devacirepvec; JX-594) for the Phase 1b clinical trial for patients with renal cell carcinoma (APP203530).

We note that the earlier trial you approved in 2016 with the same genetically modified vaccinia virus, Pexa Vec, for liver cancer (APP202601) was withdrawn early due to not meeting its end points. We were told that of the 49 NZ patients, 26 patients (53%) dropped out of the trial, which included those who withdrew, or died from the disease.

In this trial (APP202601) we note that pustules were treated but any adverse effects from them were not reported as the EPA only required reporting of adverse events if there was transmission to others. We ask -

1. Why did the EPA not require adverse event reporting regardless of transmission?
2. Has the Phase 1b clinical trial ended?

3. Why was this trial approved when the outcome of the earlier trial APP202601had such a concerning outcome?
4. Have the pustules for monkey pox been tested to confirm they are not really transmission of the Pexa Vec trials?
5. Please may we have the annual reports to the EPA as required under control 7 of the APP203530 application?

Ngā mihi,

Jon Muller
Secretary **GE Free NZ**
secretary@gefree.org.nz

cc: Claire Bleakley
President **GE Free NZ**
027 348 6731
claire@gefree.org.nz