HPV16+ Cancer Vaccine

eTheRNA immunotherapies NV is currently developing a therapeutic vaccine for HPV16+ cancers. These cancers arise from a sexually transmitted virus called, human papilloma virus type 16 (HPV16).

Vaccine Overview

- **Project Name**
  - A002
- **Stage**
  - CTA/IND
- Components
  - mRNA encapsulated in lipid nanoparticles
  - TriMix adjuvant
  - Co-presented E6 and E7 HPV16 antigens
- **Indication**
  - Recurrent/metastatic HPV16+ cancer
- **Route of administration**
  - Intravenously

HPV Overview

High risk HPVs cause about 5% of all cancers worldwide. HPV-16+ can lead to head and neck, cervical and anogenital cancers. HPV-16 (& HPV18) cause almost all cervical cancers. HPV-16 is responsible for up to 70% of all head and neck cancers, depending on the geographic location. With 5-year survival rates of only 32% and 17%, improved treatment of unresectable head and neck and cervical cancer is an area of poorly met medical need.

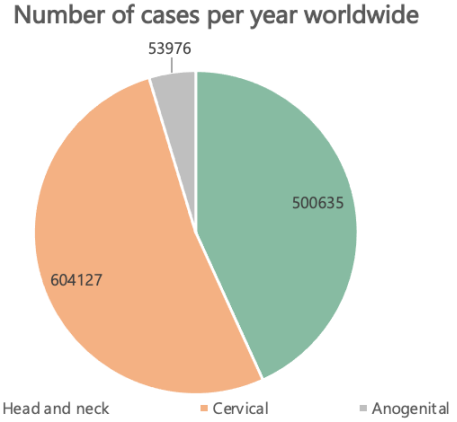
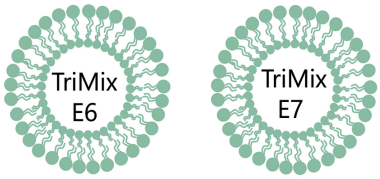


Figure 1: *Cervical cancer has the most cases per year worldwide following head and neck cancer then anogenital cancer.*

Vaccine Efficacy

Mixture of proprietary lipid nanoparticles loaded with mRNA coding for TriMix and either E6 or E7 HPV-16 antigen mRNA.



A002 is intended to treat unresectable HPV16+ cancer patients who receive anti-PD1 therapy. Preclinical experiments demonstrate that the best-in-class immune response (up to 80% of vaccine-specific CD8+ T-cells) elicited translates into potent anti-tumour activity. This effect is augmented when it is combined with anti-PD1 antibodies.

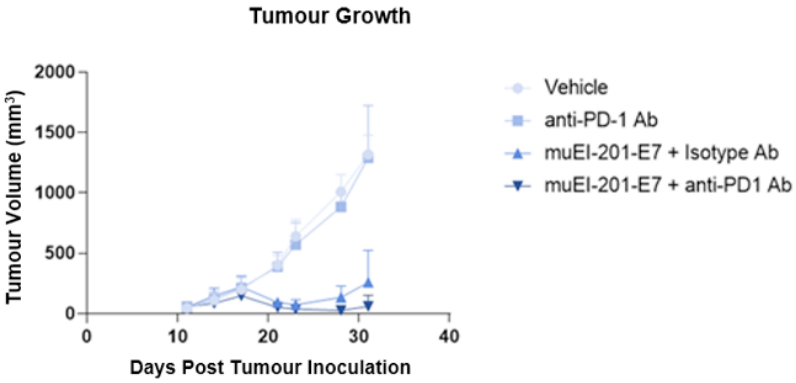


Figure 2: *Data generated in TC-1 tumour bearing C57BL/6J mice. Vaccine (5µg) administered intravenously at days 11, 18 and 25 after tumour inoculation. Anti-PD-1 (200µg) or isotype control antibody (200µg) administered intraperitoneally every 3 to 4 days starting from day 14 until day 40. Average ± SEM is shown.*

Next Steps

GLP-toxicity study in non-human primates demonstrated that A002 is well tolerated. The results of the GLP toxicity study support the **human clinical trial** application of the phase 1 study planned **to start in 2022.**

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