

Clinical Trial Fact Sheet

A Phase 1/1b, Multicenter, Open-label Trial of Oncolytic MG1 Expressing Mutant Human Papilloma Virus (HPV) E6 and E7 (MG1-E6E7), with Adenovirus Vaccine Expressing Mutant HPV E6 and E7 (Ad-E6E7) and Atezolizumab in Patients with HPV Associated Cancers (Kingfisher)

Key Information

Who may qualify?

- Patients having histologically or cytologically confirmed, HPV positive metastatic or locally advanced solid tumor (eg squamous cell carcinoma of the head and neck (SCCHN), esophagus, cervix, anal canal, vulva, penis or other solid tumor that is HPV positive) not amenable to curative intent therapy.
- For full inclusion criteria, click on the link at the bottom of page

Recruitment status

Active; no longer recruiting

Key words

• HPV, oncolytic vaccine, Ad/MG1-E6E7

cancer Princess Margaret Cancer Centre (Toronto) The Ottawa Hospital Juravinski Cancer Associated Tumours **Centre** (Hamilton) University of Miami Initiate and complete a clinical trial to Memorial Sloan evaluate the safety, biology, and antitumour activity of the oncolytic virus **Kettering Cancer Center** vaccine technology for patients with/ (New York, NY) HPV-associated tumours. MD Anderson Cancer Center (Houston, TX)

- The Eleanor N. Dana Cancer Center (Toledo, OH)
- The Billings Clinic (Billings, MT)

About the project

Novel immunotherapy agents that target the immune system in order to treat tumours are revolutionizing cancer care. However, only 10-40% of patients respond to treatment, depending on the therapeutic agent and the indication. Therefore, novel agents with unique mechanisms-of-action are needed. Oncolytic virus vaccines infect and break up particles in tumour cells while inducing lasting anti-tumour immunity by expressing tumour-associated antigens (immune-stimulating molecules).

This team of researchers has made a next-generation oncolytic virus vaccine that is designed to address a major unmet medical need: cancers associated with HPV. HPV causes virtually all cervical cancers in the world, the majority of head and neck cancers in industrialized countries, and a variety of other tumours (e.g. oesophageal and anal). Approximately 5% of the world's cancer burden is caused by HPV.

HPV-associated tumours are an ideal target for oncolytic vaccine technology as the HPV antigens are foreign to the body (therefore more likely to produce an immune response) and also drivers of tumour growth (therefore the tumour is unlikely to lose expression of the antigen). This project aims to test in a clinical trial a new immune therapeutic strategy for patients with advanced cancers having failed conventional therapies. Specifically, the team have developed an oncolytic virus vaccine technology that takes advantage of the unique biology of a certain virus discovered by members of their team.

This project will evaluate the safety and anti-tumour activity of Ad/MG1-E6E7 in patients with HPV-associated tumours. In addition, anti-E6 and E7 immune responses will be monitored on the study, potentially providing a basis for the evaluation of the oncolytic virus vaccine technology in combination with other cancer immunotherapies in the future.

For specific information to share with your doctor and care team <u>click here</u> (URL--> https://bit.ly/35CNEUL | Clinical Trial #: NCT03618953)