A QUICK GUIDE TO THE HAWK STUDY (D4193C00001)

- NMRR-15-424-25050-

A phase II, multicentre, single-arm, global study of MEDI4736 monotherapy in patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN)

PATIENTS WITH SCCHN

Worldwide, more than 500,000 people are diagnosed with head and neck cancer each year and around 70% of them are diagnosed with a locally advanced or metastatic disease. Currently there is no satisfactory therapy for patients who have failed one prior platinum containing regimen for metastasis or recurrence.

TARGETING THE ANTITUMOUR RESPONSE

Evidence suggests that SCCHN tumours create a highly immunosuppressive environment by utilising the PD-1/PD-L1 axis. Tumours overexpress PDL1 and inhibit T cell activation by binding to PD1 on the T-cell surface to prevent immune detection or destruction. Therefore, it is hypothesised that SCCHN patients may benefit from treatment with an immune-modulating agent. This study will use MEDI4736, an anti-PD-L1 antibody that may stimulate the patient's antitumour immune response by blocking the PDL1-PD1 interaction.

ALL PATIENTS WILL RECEIVE MEDI4736

All patients will be given an intravenous infusion of MEDI4736 once every two weeks. Patients will be treated with MEDI4736 for a maximum of 12 months or until confirmed disease progression, initiation of alternative therapy, development of unacceptable toxicity, patient withdrawal of consent or other discontinuation criterion is met.

Participants will then enter a follow-up stage. During this time, patients who progress after an initial response or disease stabilisation to MEDI4736 may begin treatment with another 12-month treatment period with MEDI4736.

WE'RE LOOKING FOR 112 SCCHN PATIENTS

We're looking to recruit approximately 112 adults worldwide who have:

- *Histologically confirmed recurrent or metastatic SCCHN of the oral cavity, oropharynx, hypopharynx or larynx (not nasopharyngeal cancer) not amenable to therapy with curative intent*
- *Experienced tumour progression or recurrence during or after treatment with one regimen for recurrent or metastatic disease*; regimen must have contained a platinum*
- *Confirmed PD-L1-positive SCCHN (will be confirmed during screening)*
- *At least 1 lesion ≥10 mm in the longest diameter*

  OR

- *At least 1 lymph node lesion ≥15 mm in the short axis*
- *No prior exposure to immunotherapies*
- *No history of Hep B, C or HIV*

Note: patients who have newly diagnosed untreated metastatic disease would not be eligible for this study.

**Patients who have only received chemo-radiation therapy for locally advanced disease will not be eligible. Patients who received chemo-radiation alone as part of treatment of their recurrent disease are also not eligible.*

PATIENT HEALTH IS OUR TOP CONCERN

Each patient's health will be monitored closely throughout the study. Typical assessments include physical examinations, vital signs checks, blood tests, tumour sampling, electrocardiograms and questionnaires. During the 12-month treatment stage, these visits will take place once every 2 weeks for the first 8 weeks, then once every 4 weeks. During the follow-up stage, these visits will take place once every 1 to 4 months for the first 12 months, then once every 6 months.

YOU MAY BE ABLE TO HELP US

If you think you may know of an eligible patient, please refer them to the study team. Your patients will receive excellent care throughout the study and will remain your patient for any non-study-related issues.

THANK YOU

For your time and interest

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