A QUICK GUIDE TO THE CONDOR STUDY (D4193C00003)

- NMRR-15-819-25789-

A phase II, randomised, open-label, multicentre, global study of MEDI4736 monotherapy, tremelimumab monotherapy and MEDI4736 in combination with tremelimumab 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

It is increasingly understood that the immune system is able to recognise cancers and, under some circumstances, control or even eliminate tumours. Therefore, it is hypothesised that SCCHN patients may benefit from treatment with an immune-modulating agent. The study drug will be MEDI4736, an anti-PD-L1 antibody that may stimulate the patient's antitumour immune response.

PATIENTS WILL BE RANDOMISED IN A 1:1:2 RATIO

	MEDI4736 infusion (unapproved study drug)	Tremelimumab infusion
Group 1 (60 participants)	Once every 2 weeks	
Group 2 (60 participants)		Once every 4 weeks for 7 doses, then once every 12 weeks for 2 doses
Group 3 (120 participants)	Once every 4 weeks for up to 4 doses, then every 2 weeks for up to 18 doses	Once every 4 weeks for 4 doses

Patients will be treated 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 whose disease was stable after the first 12 months but who experience disease progression will be given the option to restart their assigned regimen for up to an additional 12 months. The same treatment guidelines will apply.

Condor

WE'RE LOOKING FOR 240 SCCHN PATIENTS

We're looking to recruit approximately 240 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–negative SCCHN (will be confirmed during pre-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.

	VISITS DURING THE 12-MONTH TREATMENT STAGE												
	W*0	W2	W4	W6	W8	W10	W12	W14	W16	W18	W20	W22	W24
Group 1	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Group 2	✓	✓	✓	✓	✓		✓		✓		✓		✓
Group 3	✓	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓

	W26	W28	W30	W32	W34	W36	W38	W40	W42	W44	W46	W48	W50
Group 1	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Group 2		✓		✓		✓		✓		✓		✓	
Group 3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

**Week*

VISITS DURING THE FOLLOW-UP STAGE (AFTER COMPLETING THE TREATMENT PERIOD)								
M*1	M2	M3	M4	M6	M8	M10	M12	Every 6 months as needed
Patients will only receive infusions if their condition has deteriorated								

**Month*

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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