The ROYAL MARSDEN
NHS Foundation Trust

Clinical Trials Unit
The Royal Marsden NHS Foundation Trust
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Sutton SM2 5PT
perm.trial@rmh.nhs.uk

18.04.2023

Dear EudraCT Team,

Re: Confirmation of a lack of results for a specific trial

EudraCT number: 2014-004065-25

Protocol title: Randomised Phase II Trial of Pembrolizumab and Radiotherapy in Melanoma (PERM)

The Chief Investigator and the Sponsor Representative of the above clinical trial would like to notify you that no results will be uploaded to EudraCT because the trial was prematurely ended and as such, statistical analysis cannot be provided.

The clinical trial was prematurely ended as the funder of the study, Merck Sharp and Dohme, decided to withdraw the funding due to insufficient accrual rate.

As the study recruited only 17 patients out of the target of 234, the data collected is not sufficient for analysis, and we are not able to evidence the primary endpoint.

This is a randomised trial. The patients were randomised to receive 200mg of pembrolizumab 3 weekly either alone or in combination with a course of high dose radiotherapy. Clinical assessments were undertaken every 3 weeks on the day on which the drug was administered. The patients in the radiotherapy arm received 24Gy in 3 fractions over a course of 3 consecutive days between the first and second doses of pembrolizumab.

8 study participants were treated with pembrolizumab alone, and 9 participants were treated with combination of pembrolizumab and radiotherapy.

Further details:

Patient RM-4251-1

Trial arm assigned: pembrolizumab alone
Completed 4 cycles of pembrolizumab
Treatment stopped due to disease progression

Patient RM-4251-2

Trial arm assigned: pembrolizumab with radiotherapy
Completed 5 cycles of pembrolizumab and 3 days of radiotherapy
Treatment stopped due to toxicities

Patient IP-4251-2

Trial arm assigned: pembrolizumab with radiotherapy
Completed 4 cycles of pembrolizumab and 3 days of radiotherapy
Treatment stopped due to disease progression

Patient IP-4251-4

Trial arm assigned: pembrolizumab with radiotherapy
Completed 2 cycles of pembrolizumab and 3 days of radiotherapy
Treatment stopped due to disease progression

Patient NC-4251-1

Trial arm assigned: pembrolizumab alone
Completed 15 cycles of pembrolizumab
Treatment stopped due to disease progression

Patient NO-4251-1

Trial arm assigned: pembrolizumab alone
Completed 24 cycles of pembrolizumab
Treatment stopped due to intercurrent illness

Patient NO-4251-2

Trial arm assigned: pembrolizumab alone
Completed 8 cycles of pembrolizumab
Treatment stopped due to disease progression

Patient NO-4251-3

Trial arm assigned: pembrolizumab with radiotherapy
Completed 13 cycles of pembrolizumab and 3 days of radiotherapy
Treatment stopped due to disease progression

Patient NO-4251-4

Trial arm assigned: pembrolizumab alone
Completed 10 cycles of pembrolizumab
Treatment stopped due to disease progression

Patient NO-4251-5

Trial arm assigned: pembrolizumab with radiotherapy
Completed 10 cycles of pembrolizumab and 1 day of radiotherapy
Treatment stopped due to disease progression

Patient NO-4251-7

Trial arm assigned: pembrolizumab alone
Completed 4 cycles of pembrolizumab
Treatment stopped due to consent withdrawal

Patient WP-4251-2

Trial arm assigned: pembrolizumab with radiotherapy
Completed 9 cycles of pembrolizumab and 3 days of radiotherapy
Treatment stopped due to disease progression

Patient WP-4251-4

Trial arm assigned: pembrolizumab alone
Completed 19 cycles of pembrolizumab
Treatment stopped due to intercurrent illness

Patient WP-4251-5

Trial arm assigned: pembrolizumab with radiotherapy
Completed 30 cycles of pembrolizumab and 3 days of radiotherapy
Treatment stopped due to withdrawal (PI decision as no evidence of active disease; complete response to treatment)

Patient XF-4251-1

Trial arm assigned: pembrolizumab with radiotherapy
Completed 5 cycles of pembrolizumab and 3 days of radiotherapy
Treatment stopped due to death

Patient XF-4251-3

Trial arm assigned: pembrolizumab with radiotherapy
Completed 35 cycles of pembrolizumab and 3 days of radiotherapy
Treatment completed.

Patient XF-4251-5

Trial arm assigned: pembrolizumab alone
Completed 31 cycles of pembrolizumab
Treatment stopped due to disease progression

Serious Adverse Events

Reporting description: any SAE whether or not related to pembrolizumab, occurring from randomisation until 30 days following cessation of treatment, or the initiation of new anti-cancer therapy, whichever is earlier. The CTCAE version 4 to be used to grade each SAE, and the worst grade to be recorded.

5 SAEs were reported in the study – these are detailed in Appendix 1.

Yours sincerely,

Signature: 

Date: 18/4/23

Chief Investigator
Prof James Larkin
Consultant Medical Oncologist

Signature: 

Date: 19/4/23.

Sponsor Representative
Ms Jane Lawrence
Director of Research Operations

The Royal Marsden NHS Foundation Trust, Downs Road, Sutton, SM2 5PT

Appendix 1: Serious Adverse Events listing

Patient ID	CTCAE System Organ Class[1]	CTCAE Term[1]	CTCAE Grade[1]	Causality	Expectedness
XF-4251-1	Infections and infestations	Sepsis	G5	Unrelated	N/A
IP-4251-2	Musculoskeletal and connective tissue disorders	Bone pain	G3	Unrelated	N/A
WP-4251-5	Endocrine disorders	Other: hypophysitis related to hypopituitarism	G3	Probably	Expected
NO-4251-5	Musculoskeletal and connective tissue disorders	Back pain	G3	Unrelated	N/A
NO-4251-5	Nervous system disorders	Other: brain metastases	G3	Unrelated	N/A

[1] CTCAE v4.0