MRC Clinical Trials Unit

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UCL

Health Research Authority
Skipton House
80 London Road
London SE1 6LH

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EudraCT number: 2004-000193-31
Sponsor reference number: MRC RE06

Dear Colleague,

RE: Renal Adjuvant MultiPle Arm Randomised Trial (RAMPART): An international investigator-led phase III Multi-Arm, Multi-Stage (MAMS), multi-centre, randomised controlled platform trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse

I am writing to seek HRA approval and REC review for the RAMPART clinical trial as outlined in the IRAS application and supporting documentation enclosed.

RAMPART is an academic investigator-initiated trial sponsored by University College London. Dr James Larkin (Royal Marsden Hospital) is the Chief Investigator and the trial will be co-ordinated by the MRC Clinical Trials Unit at UCL. RAMPART is an international collaboration with sites planned in Australia, France and the US as well as the UK. Please see the protocol for the membership of the Trial Development Group (TDG), who will also form the Trial Management Group (TMG).

RAMPART is a multi-arm, multi-stage (MAMS) adaptive platform design. The trial will be initiated with three arms: a control arm of active monitoring (Arm A) and two research arms, durvalumab monotherapy (Arm B) and a combination of durvalumab and tremelimumab (Arm C) (see Figure 1 overleaf). Recruitment will initially include both intermediate and high-risk RCC patients (Leibovich score 3-11); accrual will be monitored and stop in the intermediate-risk group after 3 years or when this sub-group contributes to 25% of the total accrual target.

Kidney Cancer UK has provided independent scientific peer-review of the trial protocol and is providing a small amount of funding each year. Astra Zeneca (AZ) is providing an educational grant and free-of-charge drugs. Both UCL and AZ intend that data from the trial may be used to support a license extension for either or both of the treatment regimens being investigated in RAMPART and have therefore sought scientific advice from the FDA and EMA prior to finalisation of the trial protocol. Given the adaptive nature of the trial design, RAMPART has been designed with the feature of adding another research arm over time; any decision to do so will be discussed with the regulators prior to implementation.

I would like to thank you for considering this submission. We welcome the opportunity to respond to any comments or questions you may have.

Kind regards

Dr Angela Meade

On behalf of the RAMPART Trial Development Group

MRC Clinical Trials Unit at UCL
90 High Holborn
2nd Floor
London WC1V 6LJ
E-mail: mrcctu.rampart@ucl.ac.uk

Figure 1. RAMPART trial schema