Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**A Phase 1/2, Multicentre, Open-Label Study of Modi-1 in Patients with Breast, Head and Neck, Ovarian, or Renal Cancer** **(Short Title: The ModiFY Study)**
Study Details	This is an open-label early-phase study trialling the study drug (Modi-1/Modi-1v) vaccine both as monotherapy and (later) in combination with a checkpoint inhibitor where these are standard of care in a non-neoadjuvant setting). We are contributing triple negative breast cancers, ovarian and renal cell cancers to vaccine monotherapy. We are also contributing renal cell cancers to vaccine combined with checkpoint inhibitor therapy.
Principal Investigator PI **Sub-Investigator**	Dr Dennis Hadjiyiannakis (Consultant Oncologist, PI) Dennis.Hadjiyiannakis@lthtr.nhs.uk Dr David Cameron (Research Fellow) David.Cameron@lthtr.nhs.uk Dr Natalie Charnley (Consultant) Dr Omi Parikh (Consultant) Dr Martin Hogg (Consultant)
Research Nurse Team	Karen Jones (Senior Research Nurse) Karen.Jones4@lthtr.nhs.uk Helen Cross (Research Nurse) helen.Cross@lthtr.nhs.uk
Drug therapy	The study drug is an intradermal vaccine given in the Lancashire Clinical Research Facility with post-dosing observation before a patient is discharged. The vaccine is designed to enhance immune responses against peptides commonly expressed or upregulated by cancer cells undergoing autophagy, improving the immune system's recognition of these cancers and increasing patient response rates. There are no blinding or unblinding requirements for this study. **Adverse Events (related to vaccine)** This is a phase 1/2 study with limited human experience. Injection site reactions: The study drug is delivered via an intradermal injection. The site will be monitored prior to discharge for any local reactions. Local reactions and the possibility of hypersensitivity to the peptide may occur. There is a possibility that autoimmune disease/Rheumatoid Arthritis may worsen or develop as a consequence of the study drug. Immune-mediated toxicities may be managed by corticosteroid immunosuppression. Severe toxicities may result in treatment withdrawal. **Adverse Events (related to checkpoint inhibition)**

	As per standard protocol for checkpoint inhibitor therapies.
In the event that a patient calls this hotline for advice	Advise patient to seek medical assistance via the nearest available healthcare provider depending upon severity of symptoms. Advise patient to keep all relevant trial paperwork with them for review by treating clinician Please alert PI/Sub-I/Trial team at LancashireCRF@lthtr.nhs.uk or 01772 522031 within office hours. Contact the Oncology Registrar for further advice. For significant reactions also contact PI/Sub PI on 07512193096.