Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**The SCOPE Study**
Study Details	A Phase 2, Multicentre, Open-Label Study of SCIB1 in Patients with Advanced Unresectable Melanoma Receiving Either Nivolumab with Ipilimumab or Pembrolizumab
Principal Investigator PI Sub PI's	PI Dr Kellati Prasad Kellati.Prasad@lthtr.nhs.uk Sub-I Dr David Cameron David.Cameron@lthtr.nhs.uk
Research Nurse Team	Research Nurse Carolyn Hatch Research Nurse Karen Jones Research Nurse Elizabeth Coates Research Nurse Rosalind Szurko
Drug therapy	SCIB1 study drug is a cancer vaccine therapy. Patients will receive four IM injections of SCIB1, administered at weeks 0, 4, 7, 13, 25 and every 12 weeks thereafter until Week 85. This is in combination with standard of care CPI regimen (Pembrolizumab or Ipilimumab/Nivolumab). On days when both SCIB1 and CPI are administered, SCIB1 will be administered before CPI. Pembrolizumab will be administered at 400 mg as an IV infusion every 6 weeks until disease progression or unacceptable toxicity. Nivolumab with Ipilimumab will be administered as combination therapy 3-weekly for 4 doses then monotherapy (240mg 2-weekly over 30 mins or 480mg 4-weekly over 60 mins). The first dose of CPI will be administered at Week 1 to ensure an adequate primary immune response following the first SCIB1 dose **Blinding** This is an open-label study. There is no blinding or unblinding requirement. **Adverse Events** In earlier studies, the most common events considered related to study drug (SCIB1) are: Injection site haematoma/pain, fatigue, blurred vision, headache. Note that this occurred with a previous injection electroporation device which has been replaced for this study with the Pharmajet Stratis device.

	Adverse events for CPI are expected to be as per usual for these treatments (see trust guidance for Pembrolizumab and Ipilimumab/Nivolumab).
In the event that a patient calls this hotline for advice	Pembrolizumab protocol - Quick Reference Guide - MRSA Topical Eradication (healthierlsc.co.uk) Nivolumab protocol - https://www.healthierlsc.co.uk/application/files/7116/5772/4651/Nivolumab_July_2022.pdf Ipilimumab protocol - https://www.healthierlsc.co.uk/application/files/8615/6881/0704/melanoma_ipilumumab_v8.pdf 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.