Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**BO45230**
Study Details	A RANDOMIZED PHASE II, DOUBLE-BLIND, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF AUTOGENE CEVUMERAN PLUS NIVOLUMAB VERSUS NIVOLUMAB AS ADJUVANT THERAPY IN PATIENTS WITH HIGH-RISK MUSCLEINVASIVE UROTHELIAL CARCINOMA
Principal Investigator PI Sub PI's	Principal Investigator: Professor Alison Birtle (Alison.Birtle@lthtr.nhs.uk) Sub-Investigator: Dr Natalie Charnley (Natalie.Charnley@lthtr.nhs.uk) Sub-investigator: Dr David Cameron (David.Cameron@lthtr.nhs.uk) Tel: 01772 522031
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Drug therapy	This trial involves giving patients Nivolumab for muscle invasive bladder cancers following cystectomy. Some patients will additionally receive the trial drug (personalised vaccine Autogene Cevumeran, "Cevu"). This is an open-label study so patients will know if they have received it. The expected side-effect profile of Nivolumab is known and local guidance should be followed in relation to this. Infusion reactions and cytokine release syndrome is a potential effect of the trial medication. The primary approach to mild to moderate immune-related adverse events is supportive and symptomatic care. Cytokine Release Syndrome may present hours to days following administration and is typically characterised by flu-like symptoms including involves fever, hypotension and hypoxia, fatigue, myalgia. Diarrhoea, Vomiting and Dyspnoea have also been reported with "Cevu".
In the event that a patient calls this hotline for advice	Refer to existing protocols for additional information regarding nivolumab treatment.

	Advise patient to seek medical assistance via nearest available healthcare provider depending upon severity of symptoms. In an emergency they are to seek emergency medical attention through 999. Advise patient to keep all relevant trial paperwork with them for review by treating clinician. Further details regarding the study are available on EVOLVE electronic notes. Patients requiring admission may be reviewed by the on-call Oncology SpR/Consultant. Day time contact number of the trials unit is 01772 522031. Treatment interruption/modification may be required (Dose modification or interruption guidance is contained in the study protocol).