Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**BNT113-01 (AHEAD-MERIT)**
Study Details	An open-label Phase II randomized trial of BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first line therapy in patients with unresectable recurrent, or metastatic Head and Neck Squamous Cell Carcinoma (HNSCC) which is positive for human papilloma virus 16 (HPV16+) and expresses PD-L1
Principal Investigator PI Sub PI's	Principal Investigator: Dr Arafat Mirza (Arafat.Mirza@lthtr.nhs.uk) Sub-Investigator: Dr Agostino Cristaudo (agostino.cristaudo@lthtr.nhs.uk) Sub-investigator: Dr David Cameron (David.Cameron@lthtr.nhs.uk) Tel: 01772 522031
Research Nurse Team	Email: Lancashirecrf@lthtr.nhs.uk Tel: 01772 522031
Drug therapy	This trial involves giving patients Pembrolizumab for unresectable HPV positive head & neck cancers. Some patients will additionally receive the trial drug (vaccine BNT113). This is an open-label study so patients will know if they have received it. The expected side-effect profile of Pembrolizumab is known and local guidance should be followed in relation to this. Infusion reactions and cytokine release syndrome (cytokine storm) is a potential effect of BNT113. 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. Shaking/rigors, nausea and vomiting have also been reported with BNT113.
In the event that a patient calls this hotline for advice	Refer to head & neck protocols for additional information regarding pembrolizumab 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. If out of hours escalation is required, please alert PI/Co-I on the above emails or 07394097123 (baton phone). Treatment interruption/modification may be required (Dose modification or interruption guidance is contained in the study protocol).