Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**BNT327-06**
Study Details	**Trial title:** A Phase II/III, multisite, randomized master protocol for a global trial of BNT327 in combination with chemotherapy and other investigational agents in first-line non-small cell lung cancer **Brief lay title:** Safety, preliminary effectiveness of BNT327, an investigational therapy for patients with small-cell lung cancer in combination with chemotherapy **Trial phase:** Phase II/III **Indication:** First line NSCLC **Investigational medicinal product (IMP):** BNT327 (also referred to as PM8002)
Principal Investigator PI Sub PI's	Principal Investigator: Dr TC Lam (Taichung.lam@lthtr.nhs.uk) Sub-investigator: Dr David Cameron (David.Cameron@lthtr.nhs.uk) Tel: 01772 522031
Research Nurse Team	Lead nurse: Allan Brown (Allan.Brown@lthtr.nhs.uk) Tel: 01772 522031
Drug therapy	This trial involves treating patients with the investigational product (IMP) BNT327 or Pembrolizumab alongside Carboplatin and Pemetrexed or Paclitaxel. Please refer to treatment & adverse event guidelines for existing medications where appropriate. The IMP is a combination of VEGF and PD-L1 inhibitory agents. As such, a range of adverse events may occur. **PD-L1 associated:** Checkpoint inhibitor associated adverse events including rash, diarrhoea, pneumonitis, hepatitis, colitis, nephritis, arthritis and thyroid dysfunction are possible. **VEGF associated:** VEGF inhibition is associated with hypertension, proteinuria, poor wound healing, and intestinal perforation.
In the event that a patient calls this hotline for advice	Refer to SoC protocol for additional information regarding SoC 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. 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).