Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**BNT327-03**
Study Details	**Trial title:** A Phase III, multisite, double-blinded randomized trial of BNT327 in combination with chemotherapy (etoposide/carboplatin) compared to atezolizumab in combination with chemotherapy (etoposide/carboplatin) in participants with first-line extensive-stage small-cell lung cancer **Brief lay title:** Safety and effectiveness of BNT327, an investigational therapy in combination with chemotherapy for patients with untreated small-cell lung cancer **Trial phase:** Phase III **Indication:** First line Extensive SCLC **Investigational medicinal product (IMP):** BNT327 in combination with Etoposide/Carboplatin vs Atezolizumab in combination with Etoposide/Carboplatin.
Principal Investigator PI Sub PI's	Principal Investigator: Dr Amin Ali (Amin.Ali@lthtr.nhs.uk). Emergency contact below. Consultant Sub-Investigators: Dr Devleena, Dr TC Lam, Professor Ruth Board, Dr Sin Lau, Professor Dennis Yiannakis Sub-investigator: Dr David Cameron (David.Cameron@lthtr.nhs.uk) Tel: 01772 522031 (Working hours)
Research Nurse Team	Lead nurse: Jean Hutchinson (Sia.Hutchinson@lthtr.nhs.uk) Tel: 01772 522031 (Working hours)
Drug therapy	This trial involves treating patients with the investigational product (IMP) BNT327 or Atezolizumab, alongside Carboplatin and Etoposide. Please refer to treatment & adverse event guidelines for Carboplatin/Etoposide where appropriate. Note that treatment with BNT327 or Atezolizumab is blinded to the investigators. If **unblinding** is required, see below. 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	Emergency contact: PI Dr Amin Ali If unavailable please contact one of the Sub-Investigators via switchboard Sub-I Dr TC Lam Sub-I Professor Ruth Board Sub-I Dr Sin Lau Sub-I Dr Devleena Sub-I Professor Dennis Yiannakis 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. Daytime 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). The principal Investigator and Sub-Investigators should have access to this via the NHS EDGE system.
Emergency Unblinding	This trial involves the blinded administration of BNT327 or Atezolizumab. In the event of an emergency, it may be necessary to unblind which treatment a patient has received. This action should not be taken unless necessary. 1.) Unblinding is performed via the 4Gclinical "Prancer" account (https://biontech.4gclinical.com). Investigators will receive an account activation email at study setup. 2.) To unblind a patient select Main Menu > Unblinding > Unblind Patient. 3.) Enter patient ID and click next to continue. 4.) Click 'submit' to complete the unblinding.