

Clinical Trials Summary for out of hours Important Reference

Acronym study title	BNT324-01
Study Details	Trial title: A Phase Ib/II, multi-site, open-label, two-part trial to evaluate the efficacy, safety, pharmacokinetics, and recommended combination dose of BNT324 with BNT327 in participants with advanced lung cancer Brief lay title: A study to investigate the safety of BNT 324 and BNT327 in advanced lung cancer patients (BNT324-01) Trial phase: Phase Ib/II Indication: Advanced lung cancer (first line & second line +) Investigational medicinal product (IMP): BNT327 (also referred to as Punitaming) + BNT324
Principal Investigator PI Sub PI's	Principal Investigator: Dr Sin Lau (dr.lau@nhs.net) Sub-investigator: Prof Dennis Hadjiyiannakis (Dennis.Hadjiyiannakis@lthtr.nhs.uk) Dr Amin Ali (Amin.Ali@LTHTR.nhs.uk) Dr Tai-Chung Lam (TaiChung.Lam@lthtr.nhs.uk) Dr Devleena (Devleena.Devleena@LTHTR.nhs.uk) Tel: 01772 522031
Research Nurse Team	Lead nurse: Elizabeth Coates (elizabeth.coates@lthtr.nhs.uk) Tel: 01772 522031
Drug therapy	This trial involves treating patients with the investigational product (IMP) BNT327 alongside another IMP BNT324. The IMP BNT327 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. The IMP BNT324 is a B7-H3 antibody drug conjugate (ADC). Associated adverse events include gastrointestinal toxicities, interstitial lung disease/pneumonitis, corneal and skin toxicities, infusion-related reactions.

In the event that a patient calls this hotline for advice	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).
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