

<p><b>Clinical Trials Summary for out of hours Important Reference</b></p>
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<b>Acronym study title</b>	<b>BNT327-01</b>
<b>Study Details</b>	<p><b>Trial title:</b> A Phase II, multi-site, randomized, open-label, parallel group trial of BNT327 in combination with chemotherapy for participants with untreated extensive-stage small-cell lung cancer and participants with previously treated small-cell lung cancer.</p> <p><b>Brief lay title:</b> Safety, preliminary effectiveness of BNT327, an investigational therapy for patients with small-cell lung cancer in combination with chemotherapy</p> <p><b>Trial phase:</b> Phase II</p> <p><b>Indication:</b> Untreated extensive-stage small-cell lung cancer and previously treated small-cell lung cancer Investigational medicinal product (IMP): BNT327 (also referred to as PM8002)</p>
<b>Principal Investigator PI Sub PI's</b>	<p>Principal Investigator: Prof Dennis Hadjiyiannakis (<a href="mailto:Dennis.hadjiyiannakis@lthtr.nhs.uk">Dennis.hadjiyiannakis@lthtr.nhs.uk</a>) Tel: 01772 523736</p> <p>Sub-Investigator: Prof Ruth Board (<a href="mailto:Ruth.board@lthtr.nhs.uk">Ruth.board@lthtr.nhs.uk</a>) Tel: 07842634191 (sec)</p> <p>Sub-investigator: Dr David Cameron (<a href="mailto:David.Cameron@lthtr.nhs.uk">David.Cameron@lthtr.nhs.uk</a>) Tel: 01772 522031</p>
<b>Research Nurse Team</b>	<p>Email: <a href="mailto:Lancashirecrf@lthtr.nhs.uk">Lancashirecrf@lthtr.nhs.uk</a> Tel: 01772 522031</p>
<b>Drug therapy</b>	<p>This trial involves treating patients with the investigational product (IMP) BNT327 alongside Carboplatin &amp; Etoposide, Paclitaxel, or Topotecan. Please refer to treatment &amp; adverse event guidelines for existing medications where appropriate.</p> <p>The IMP is a combination of VEGF and PD-L1 inhibitory agents. As such, a range of adverse events may occur.</p> <p><b>PD-L1 associated:</b> Checkpoint inhibitor associated adverse events including rash, diarrhoea, pneumonitis, hepatitis, colitis, nephritis, arthritis and thyroid dysfunction are possible.</p> <p><b>VEGF associated:</b> VEGF inhibition is associated with hypertension, proteinuria, poor wound healing, and intestinal perforation.</p>

<p><b>In the event that a patient calls this hotline for advice</b></p>	<p>Refer to SoC protocol for additional information regarding SoC treatment.</p> <p>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.</p> <p>Advise patient to keep all relevant trial paperwork with them for review by treating clinician.</p> <p>Patients requiring admission may be reviewed by the on-call Oncology SpR/Consultant.</p> <p>Day time contact number of the trials unit is 01772 522031.</p> <p>If out of hours escalation is required, please alert PI/Co-I on the above emails or 07512193096 (baton phone).</p> <p>Treatment interruption/modification may be required (Dose modification or interruption guidance is contained in the study protocol).</p>
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