Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	TROPION-Lung10 A Phase III, Randomised, Open-label, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Rilvegostomig (AZD2936) or Rilvegostomig Monotherapy Versus Pembrolizumab Monotherapy for the First-line Treatment of Participants With Locally-advanced or Metastatic Non-squamous NSCLC With High PD-L1 Expression (TC ≥ 50%) and Without Actionable Genomic Alterations
Study Details	Participants will be randomised 2:1:2 to: Arm 1: Dato-DXd 6mg/kg IV infusion + Rilvegostomig 750mg IV infusion every 3 weeks on Day 1 of each cycle. At least 1 hour between infusions. Arm 2: Rilvegostomig monotherapy 750mg IV infusion every 3 weeks on Day 1 of each cycle. Arm 3: Pembrolizumab monotherapy 200mg IV infusion every 3 weeks on Day 1 of each cycle for maximum 35 cycles. The visit frequency will be every 3 weeks during the treatment period. Dato-DXd IV infusion: 90 (± 10) minutes for the first infusion, minimum 30 minutes for subsequent infusions. After the content of the IV bag is administered, the IV line will be flushed with a volume of 5% dextrose for injection equal to the IV line volume, at the same rate as infusion according to local practices, to ensure the full dose is administered. Rilvegostomig IV infusion: 75 (± 15) minutes. After the content of the IV bag is administered, the IV line will be flushed with a volume of 0.9% sodium chloride for injection or 5% dextrose for injection equal to the IV line volume, at the same rate as infusion according to local practices, to ensure the full dose is administered. Dato-DXd must be administered before other study interventions in this study. Other study interventions should not be co-administered with Dato-DXd through the same infusion line. Two consecutive doses of Dato-DXd must be administered at least 18 days apart.
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<table>
<tr><td>Research Nurse Team</td><td>Sirjana Devkota
Carolyn Hatch (back up Research Nurse)</td></tr>
<tr><td>Drug therapy</td><td>
Table 10 Investigational Products
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<tr><th>Study intervention</th><th>Dato-DXd</th><th>Rilvegostomig</th><th>Pembrolizumab</th></tr>
<tr><td>Intervention name</td><td>Dato-DXd</td><td>Rilvegostomig</td><td>Pembrolizumab</td></tr>
<tr><td>Type</td><td>ADC</td><td>Biologic</td><td>Biologic</td></tr>
<tr><td>Dosage form</td><td>Lyophilised powder for concentrate for solution for infusion</td><td>Concentrate for solution for infusion</td><td>Concentrate for solution for infusion</td></tr>
<tr><td>Unit dose strength(s)</td><td>100 mg/vial (20 mg/mL)</td><td>750 mg/vial (50 mg/mL)</td><td>100 mg (25 mg/mL)</td></tr>
<tr><td>Dosing regimen</td><td>6 mg/kg q3w</td><td>750 mg q3w</td><td>200 mg q3w</td></tr>
<tr><td>Route of administration</td><td>i.v. infusion</td><td>i.v. infusion</td><td>i.v. infusion</td></tr>
<tr><td>Use</td><td>Experimental</td><td>Experimental</td><td>Active comparator</td></tr>
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<tr><td>In the event that a patient calls this hotline for advice</td><td>Contact the PI or sub-investigators via Hospital Switchboard</td></tr>
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