

Clinical Trials Summary for out of hours Important Reference

Study Title	Tropion – 04 Urothelial Study
Study Summary	A Phase III, Open-Label, Randomised, Multicentre, Global Study of Adjuvant Datopotamab Deruxtecan in Combination with Rilvegostomig in Participants with High-risk Muscle Invasive Urothelial Carcinoma
Principal Investigator	Prof Alison Birtle
Research Team responsible for the Study	Amanda Cook Tel 01772 524656.
Drug therapy	Arm 1: Dato-DXd + rilvegostomig Participants in Arm 1 will receive 6 mg/kg Dato-DXd as intravenous (IV) infusion every 3 weeks (Q3W) of Day 1 of every 21-day cycle for 9 cycles (approximately 6 months; can be extended based on the Investigator assessment of tolerability up to 17 cycles or up to 1 year) and rilvegostomig 750 mg IV for 17 cycles or up to 1 year (whichever occurs first) starting Day 1 of each cycle Q3W. Arm 2: Dato-DXd monotherapy Participants in Arm 2 will receive 6 mg/kg Dato-DXd as IV infusion Q3W of Day 1 of every 21-day cycle for 9 cycles (approximately 6 months; can be extended based on the Investigator assessment of tolerability up to 17 cycles or up to 1 year). Arm 3 (SoC): nivolumab or durvalumab or EV + pembrolizumab Participants in Arm 3 will receive nivolumab 240 mg IV every 2 weeks (Q2W) or 480 mg IV every 4 weeks (Q4W) up to 1 year or durvalumab 1500 mg IV Q4W up to 8 cycles (or at a dose of 20 mg/kg Q4W in participants who weigh ≤ 30 kg) or EV 1.25 mg/kg D1, D8 Q3W up to 6 cycles + pembrolizumab 200 mg IV Q3W up to 14 cycles or 400 mg IV every 6 weeks (Q6W) up to 7 cycles per local label. Adjuvant treatment assignment will be based on the participant's neoadjuvant therapy.

ACTION to take if a patient calls this hotline/present at ED	Dr Birtle (Principle Investigator) Contact via switch Dr Charnley (Sub I) contact Via switch Instructions on red triangle on Haris Flex (LTHTR) Mon-Fri 8am-5pm Research Team tel 01772 524656.