

**Clinical Trials Summary for out of hours
Important Reference**



**Lancashire Teaching
Hospitals**
NHS Foundation Trust

Acronym study title	<p>MORAb-202-G000-201 Study</p> <p>A Multicentre, Open-Label Phase 1/2 Trial Evaluating the Safety, Tolerability, and Efficacy of MORAb-202, a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC) in Subjects with Selected Tumor Types</p>
Study Details	<p>This study involves the use of an antibody-chemotherapy conjugate MORAb-202 in Endometrial and Ovarian cancer patients. This is open label without the use of placebo. It is intended that this drug will be given in the Lancashire Clinical Research Facility (LCRF) in the Avondale unit, RPH.</p> <p>The drug will be given at roughly the same dose spread over one, two or three weeks out of every three depending on the cohort the patient is randomised to. Patients having the study drug once every three weeks will also be given corticosteroids to take on days 8, 9 and 10.</p>
Principal Investigator PI Sub PI's	<p>PI: Professor Dennis Hadjiyiannakis (Dennis.Hadjiyiannakis@lthtr.nhs.uk)</p> <p>Sub Investigator: Dr David Cameron (David.Cameron@lthtr.nhs.uk)</p>
Research Nurse Team	<p>Lead Nurse: Rosalind Szurko (Rosalind.Szurko@lthtr.nhs.uk)</p> <p>Elizabeth Coates</p> <p>Karen Jones</p> <p>CTSO: Mathew Anuj</p>
Drug therapy	<p>Investigational drug: MORAb-202 (farletuzumab ecteribulin; FZEC) is an antibody drug conjugate (ADC) consisting of farletuzumab, a humanized monoclonal antibody that binds to the folate receptor alpha (FRA), paired with eribulin (E7389) mesylate, a microtubule dynamics inhibitor, via a cathepsin B-cleavable linker.</p> <p>Serious Adverse Events</p> <p>Interstitial Lung Disease (ILD) is an SAE that has been seen in previous phases of the study. The current dose has been reduced in attempt to reduce incidence. The study protocol gives guidance on the management</p>

	<p>of suspected ILD and patients given a higher dose of the study drug will be given prophylactic steroids during treatment.</p> <p>Common Adverse Events (>10%)</p> <p>Pyrexia LFT derangement Nausea Headache Malaise Neutropenia/Leukopenia Anaemia Diarrhoea/Constipation Nasopharyngitis</p> <p>Infusion related reactions (including Cytokine Release Syndrome [CRS]) are a possibility and may present hours or days after treatment. If required, teams should refer to further information available on the iQemo oncology system for eg local guidelines for CRS.</p>
<p>In the event that a patient calls this hotline for advise</p>	<p>Advise patient to seek medical assistance via nearest available healthcare provider depending upon severity of symptoms. 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. Highlighted above are adverse events of likely occurrence/special interest.</p> <p>Dr Yusef Haider and Dr Kathryn Prior are Respiratory Consultants attached to the study in case of Respiratory related Adverse events eg Pneumonitis/Interstitial Lung Disease.</p> <p>Daytime contact number of the trials unit is 01772 522031. If out of hours escalation is required, please alert PI/Co-I on the above email addresses. Treatment interruption/modification may be required.</p>