Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	TROFUSE – MK2870-022
Study Details	This is a Phase 3, randomized, parallel-group, open-label, multisite study of Sacituzumab Tirumotecan maintenance treatment with or without bevacizumab versus SoC after second line carboplatin-based doublet chemotherapy in participants with PSROC. Participants must have PSROC with radiographic evidence of disease progression >180 days after the last dose of first-line platinum-based chemotherapy for OC, and according to investigator assessment, PARP inhibitor second-line maintenance treatment is not the preferred option for the participant. Prior anti-PD-1/anti-PD-L1, bevacizumab, and PARP inhibitor use, and prior secondary debulking surgery are permitted. The interval between the last dose of second-line chemotherapy and randomization must be ≤10 weeks. Eligible participants will be stratified by planned use of bevacizumab (yes vs no), BRCA status (wild type vs mutant), TROP2 expression (low vs medium + high), and response to second-line therapy at time of screening (NED vs CR or PR vs SD). In Part 2, approximately 750 participants will be randomized to 1 of the following 2 treatment arms in a 1:1 ratio: Arm 1: Sacituzumab tirumotecan 4 mg/kg IV q2w on Days 1, 15, and 29 of every 6-week cycle until disease progression, prohibitive toxicity, or other protocol-defined reason for discontinuation of study intervention Arm 2: SoC Observation **(We will not be using Bevacizumab at this site)**
Principal Investigator + Sub PI's	**PI –** Dr Dennis Yiannakis **Sub I's** – Dr Hogg + Dr David Cameron
Research Nurse Team	**Research Nurse –** Jessica Westney **Back up Nurse –** Rashmi Madan **CTSO –** Nathan Fish **Back up CTSO –** Andy Martyniak
Drug therapy	Sacituzumab tirumotecan is an ADC consisting of 3 major components: 1) a humanized antihuman TROP2 mAb of IgG1 class; 2) an ADC-coupling linker with a methyl sulfonyl moiety as the leaving group; and 3) a cytotoxic drug in the class of topoisomerase 1 inhibitors, KL610023. The DAR of sacituzumab tirumotecan is 7.4. Sacituzumab tirumotecan is designed to enhance the binding between the antibody and linker, which can prolong the half-life of ADC molecules in serum The planned dose of sacituzumab tirumotecan for participants in Part 1 and Part 2 Arm 1 of this study is 4 mg/kg.
In the event that a patient calls this hotline for advise	Contact the PI or sub-Investigators via hospital switchboard