

POSTER SESSION 11: New combinations (agents and modalities)

P11.1

A Phase Ib/IIa Study to Evaluate Safety and Activity of Oregovomab and Nivolumab in Women with Recurrent Ovarian Cancer (ORION-01)

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Background: Oregovomab is a monoclonal antibody specific for Ca 125, a tumour associated antigen expressed by more than 80% of advanced epithelial ovarian cancers (EOC). Nivolumab is a fully human monoclonal antibody that targets programmed death-1. Both agents are clinically active in advanced EOC as monotherapy. We hypothesize that the combination will elicit a systemic Ca 125 specific T cell response in a manner that is synergistic, safe and clinically efficacious.

Methods: ORION-01 is an open-label, single-arm, phase Ib/IIa, single center study with dose finding and dose expansion parts to characterize the safety and tolerability of Oregovomab in combination with Nivolumab and to establish the recommended dose for expansion (RDE). Co-primary endpoint is to evaluate the antitumor activity of this combination as assessed by overall response rate (ORR) per GCIG criteria and progression free survival. Patients with histologically confirmed epithelial ovarian carcinoma, fallopian tube and primary peritoneal carcinoma who have received 2 prior lines of cytotoxic chemotherapy are eligible for this study. Secondary endpoints include ORR per immune related response criteria, disease control rate, ORR in EOC subtypes and overall survival. Correlative studies will be performed to assess changes in immune-related pharmacodynamics characteristics at baseline and post treatment. A modified "3+3" design for dose escalation will be employed. A minimum of 6 and maximum of 18 patients will be enrolled in the dose finding part starting at a dose of 2mg every 4 weekly of Oregovomab in combination with 240mg of Nivolumab every 2 weekly. Three patients will initially be enrolled and an additional 3 if ≤ 1 dose limiting toxicity (DLT) is observed. If ≤ 1 DLT is observed then this dose level will be the RDE. Two lower dosages of Oregovomab (1mg every 4 weeks and 0.5mg every 4 weeks) are specified in case of excessive toxicities. An additional 14 patients are to enrol in the dose expansion part once RDE is determined. As per May 2017, 2 patients have been enrolled onto cohort 1. Clinical trial information: NCT03100006