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RANDOMIZED PHASE III TRIAL ON NIRAPARIB-TSR-042 (DOSTARLIMAB) VERSUS PHYSICIAN'S CHOICE CHEMOTHERAPY IN RECURRENT OVARIAN, FALLOPIAN TUBE, PRIMARY PERITONEAL CANCER PLATINUM RESISTANT PATIENTS: NITCHE TRIAL(MITO 33)

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Objectives Platinum resistant ovarian cancer (OC) patients have a poor prognosis, and few treatment options are available. Preclinical and clinical data demonstrated that the combination PARP inhibitors with immune checkpoint inhibitors could have a synergistic antitumor activity in this setting of patients. MITO 33 trial will assess the hypothesis that the combination niraparib/dostarlimab therapy is effective in increasing overall survival (OS), progression free survival (PFS) and time to first subsequent therapy with respect to chemotherapy alone.

Methods Recurrent platinum resistant OC will be randomized 1:1 to receive: -Arm A: pegylated liposomal doxorubicin 40 mg/mq d1q28, weekly paclitaxel 80 mg/mq d1,8,15q28, gemcitabine 1000 mg/mq d1,8,15q28 or topotecan 1.25 mg/mq d1-5q21; -Arm B: dostarlimab 500 mg every 3 weeks for 4 cycles, then 1000 mg every 6 weeks + niraparib 300 mg or 200 mg daily. Patients will be stratified according to homologous recombination deficiency status (positive vs negative) evaluated with Foundation One CDx LOH test, PD-L1 status, previous immunotherapy, previous PARPi treatment and Bevacizumab therapy. Endpoints Primary Endpoint: OS Secondary Endpoints: PFS; Time to First Subsequent Therapy and Objective Response Rate; Safety and Tolerability of Dostarlimab plus Niraparib Exploratory Objective: relationship between PD-L1 expression and the efficacy of niraparib/dostarlimab treatment; relationship between lymphoid or myeloid-derived suppression cells or T-regulatory cells (T-regs) and response to niraparib/dostarlimab treatment

Results Trial in progress: there are no available results at the time of submission

Conclusions Trial in progress: there are no available conclusions at the time of submission.

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PHASE 3 STUDY ASSESSING THE EFFICACY OF ADDING AL3818 (CATEQUENTINIB DIHYDROCHLORIDE, ANLOTINIB HYDROCHLORIDE) TO CHEMOTHERAPIES IN SUBJECTS WITH PLATINUM RESISTANT AND REFRACTORY OVARIAN CARCINOMA

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Objectives AL 3818 is a novel, orally administered, small molecule tyrosine kinase inhibitor, that shows highly selective inhibition of fibroblast growth factor receptor (FGFR) and vascular endothelial growth factor receptor (VEGFR). The primary objective of this Phase 3 study is to evaluate the efficacy of AL3818 in combination with chemotherapy in patients with platinum resistant and refractory ovarian carcinoma.

Methods The study is a phase 3, multi-center, randomized trial at 1:1 ratio with active control designed to evaluate the efficacy and safety of AL3818 plus background chemotherapy treatment (Active Arm) vs. background chemotherapy treatment alone (Control Arm), where one of three background treatments, weekly paclitaxel, pegylated liposomal doxorubicin (PLD), or topotecan is utilized. Patients with a diagnosis of platinum resistant or platinum refractory ovarian carcinoma requiring third line, or any further line treatment are eligible for enrollment. The regimen is a 21-day cycle with oral AL3818 at 8 mg administered on days 8–21, with days 1–7 off combining with one of the three chemotherapies in Active Arm. Maintenance monotherapy with AL3818 is an option if chemotherapy is discontinued. The primary objective of this study is to evaluate the efficacy between the Active Arm and Control Arm as measured by the primary endpoint of Progression Free Survival (PFS). The study is opening in US, UK, ES, IT and Asia. Clinical trial information: NCT02584478.

Results There are no available results at the time of submission.

Conclusions There are no available results at the time of submission.