with recurrent EOC following niraparib 1LM approval, and that 1LM approval did not markedly change the profile of patients receiving niraparib maintenance therapy in a 2L setting.

Introduction/Background AL3818 is a novel, orally administered, small molecule tyrosine kinase inhibitor. The primary objective of this phase 2 study is to evaluate the efficacy of AL3818 in combination with chemotherapies in patients with platinum resistant ovarian carcinoma. Patients with a diagnosis of platinum resistant ovarian carcinoma requiring second line or further treatment with chemotherapy were eligible for enrollment. The regimen was a 21-day cycle with oral AL3818 at 8 mg administered on days 8–21, with days 1–7 off. Chemotherapy options included weekly paclitaxel, pegylated liposomal doxorubicin (PLD), and topotecan. Maintenance monotherapy with AL3818 was an option if chemotherapy was discontinued.

Results Most patients were heavily pre-treated with median prior 4 (1–11) lines. At the cut-off date April 8, 2021, n=51 patients with platinum resistant ovarian cancer were enrolled and n=46 were evaluable, 29 of n=46 were treated with weekly paclitaxel. The objective response rate (ORR) and disease control rate (DCR) in intention to treat patient population were 43% (20/46) and 91% (42/46) for n=46 patients, and 55% (16/29) and 90% (26/29) for weekly paclitaxel patients. Median duration of response (DOR) was 5.94 months for n=46 patients and 6.43 months for weekly paclitaxel patients. Median progression free survival (PFS) was 6.27 months for n=46 patients and 6.67 months for weekly paclitaxel patients. Common treatment emergent adverse events (TEAE) included: abdominal pain (14%), alopecia (16%), constipation (10%), cough (12%), diarrhea (50%), dizziness (10%), dry skin (10%), epistaxis (18%), dyspnea (16%) fatigue (64%), fever (10%), headache (20%), hypertension (10%), anorexia (10%), oral mucositis (12%), nausea (52%), neutropenia (12%), vomiting (26%).

Conclusion AL3818 has demonstrated positive combined synergic efficacy with chemotherapies in platinum resistant ovarian cancer patients. These combination regimens are well tolerated in a heavily pre-treated population and a phase 3 registration study is ongoing (NCT02584478).