year CS as the Kaplan-Meier probability of surviving an additional 5 years (from diagnosis), given no OS event in the previous x years, adjusted for expected mortality by age and sex from U.S. life tables.

Results Median age was 60 years and 69% of patients were Caucasian. Relative 5-year survival was 41.3% overall, and decreased with increasing stage (71.2% for stage I vs. 26.0% for stage IV). CS did not improve with previous survival.

Conclusions Overall, survival rates were lower than those previously reported from Surveillance, Epidemiology, and End Results (SEER) data, and prognosis in ovarian cancer remains poor. Differences in estimates may reflect differing demographics, clinical characteristics, and treatment patterns. In contrast to prior studies, CS did not improve with time already survived. Our previous research in this sample suggests that time survived progression-free, specifically, may improve prognosis. Further research in diverse datasets is needed.

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SAFETY AND ACTIVITY OF THE ANTI-MESOTHELIN ANTIBODY–DRUG CONJUGATE ANETUMAB RAVTANSINE IN COMBINATION WITH PEGYLATED-LIPOSOMAL DOXORUBICIN IN PLATINUM-RESISTANT OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER

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Introduction Treatment options for platinum-resistant ovarian cancer (PROC) remain a high medical need. Mesothelin is highly expressed in PROC. Anetumab ravtansine (ARv) is an antibody–drug conjugate that selectively targets mesothelin, consisting of a fully human anti-mesothelin monoclonal antibody conjugated to the cytotoxic maytansinoid tubulin inhibitor DM4.

Methods This phase Ib, open-label, dose-escalation (modified 3 +3 design, n=9) and expansion study (n=56) evaluated the safety/tolerability and clinical activity of ARv and pegylated liposomal doxorubicin (PLD, 30 mg/m² Q3W) in PROC. Mesothelin expression was assessed by central immunohistochemistry. Adverse events, tumor response (RECIST v1.1), and progression-free survival (PFS) were determined. Biomarker samples were assessed by ELISA, next-generation sequencing, and expression profiling.

Results ARv/PLD combination was safe and tolerated. No DLT was observed. MTD of ARv was 6.5 mg/kg Q3W. The most common ARv-related adverse events were nausea (38.5%), decreased appetite (30.8%), corneal disorder (29.2%), fatigue (29.2%), diarrhea (24.6%), and AST increase (21.5%).

In all measurable or evaluable patients (n=65), objective response rate (ORR) was 28% (95% CI 16.0–38.5%), including one complete and 17 partial responses with a median PFS of 5.1 months. In an exploratory subset of patients (n=19) who received ≤3 prior lines of therapy with high mesothelin expression, the ORR was 42% with a median duration of response of 36 weeks. Median PFS was 8.5 months.

Conclusions/Implications These results established the RP2D, schedule, and mesothelin-positive target population of the ARv/PLD combination for the phase III study in PROC. Molecular profiling and correlation with observed clinical activity will be presented.