abstracts

[55%; 87%] in wP arm (arm A) and wP+bev (arm B). Median PFS were 14.7 and 14.9 months, in arm A and B respectively. In wP arm 50% of pts received bev alone at cross over, with median PFS of 7.3 months. Median TFST were 28.5, 33.6 and 33.6 months, in arm A + cross over bev, arm A w/o crossover and arm B respectively. Most frequent AE (all grade) were: hypertension in 78% of pts wP vs 93% of pts wP+Bev, fatigue (63% vs 78%), neuropathy (56% vs 74%), proteinuria (13% vs 63%), bleeding (16% vs 59%), alopecia (34% vs 56%), vomiting (16% vs 7%). Grade 3/4 AEs were reported in 10 arm wP vs 12 pts in arm wP+Bev.

Table: 934O			
Arms	ORR	SD	PD
wP	8(25%)	17(53%)	7(22%)
wP+Bev	12(44%)	12(44%)	3(11%)

Conclusions: A randomized trial is feasible in rare cancer with a strong international collaboration. wP confirmed as active drug in SCT. Bev added to wP tends to increase ORR compared to wP alone but failed to significantly improve PFR-6 nor PFS in relapsed SCT pts.

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9340 Alienor/ENGOT-ov7 randomized trial exploring weekly paclitaxel (wP) + bevacizumab (bev) vs wP alone for patients with ovarian sex cord tumors (SCT) in relapse

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Background: Ovarian SCT tend to respond poorly to chemotherapy (CT). We explored the efficacy of wP with or w/o bev in a randomized 1:1 phase II trial in patients (pts) with relapse who were not candidate to surgery & after > 1 line of platinum based CT.

Methods: Primary endpoint is the PFS rate at 6 months (PFR-6). Pts in the wP arm were allowed to receive bev alone at progression. A Bayesian approach allowed continuous monitoring PFR-6 with sequential analyses planned every 20 pts to allow early stopping for efficacy. wP+Bev will be considered interesting if the probability is > 0.9 to show that the estimated PFR-6 in wP+Bev is higher than in wP arm.

Results: From 02/13 to 10/16, 60 pts with SCT (52 AGCT (Adult Granulosa cell tumor), 2 SLT (Sertoli Leydig tumor), 6 other) were randomized. All pts had recurrent disease and were previously treated with CT (47 pts received ≤ 2 lines). Baseline characteristics were well balanced between the 2 arms. 17 pts (28%) received prior hormonal therapy. Platinum-free interval (PFI) was \geq 12 months in 21 pts (66%) and 22 (79%) in the wP and wP +bev group, respectively. The PFR-6 [95% CI] was 71% [55%; 84%] vs 72%