Results: The initial pilot-tested WOMAN-PRO instrument had a scale CVI of 0.98 based on six patients rating and a scale CVI of 0.92 based on six clinical experts' assessment. Clinical experts' assessments of 34 items showed excellent CVI ranging from 0.83 (15 items) to 1.0 (19 items). The remaining 3 items had a low CVI of 0.66. Patients assessment of 36 items showed excellent CVI of 0.83 (3 items) to 1.0 (33 items). The remaining item had a low CVI of 0.66. The content validity index and the comments from the initial piloting of the provisional instrument resulted in the decision to delete two items, revise three items, add one item and reduce the response options from five to four categories. The revised WOMAN-PRO showed an excellent item and scale CVI of 1.0.
Conclusions: The potential use of the WOMAN-PRO instrument in clinical practice offers patients guidance in early recognizing and self-assessing symptoms and related distress. The instrument provides clinicians with systematic information about key symptoms from a patient perspective and women's unmet informational needs related to assessing and managing symptoms in daily live. If the results of further ongoing psychometric testing are promising, the WOMAN-PRO will provide a useful outcome measure for clinical trials examining the post-surgery symptom experience in women with vulval neoplasia.

8029 POSTER

Health-Related Quality of Life (HRQoL)/Patient Reported Outcomes (PRO) of Patients (pts) With Partially Platinum Sensitive (PPS) Recurrent Ovarian Cancer (ROC) Treated in a Randomized Phase III Trial of Trabectedin and Pegylated Liposomal Doxorubicin (PLD) Vs PLD Alone (OVA-301) − an Exploratory Analysis

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Background: OVA-301 is a large randomized trial that demonstrated OS benefit (Monk B. 2011) of trabectedin plus PLD (T+P) *vs* PLD in PPS ROC pts.
Methods: This analysis provides an evaluation of PRO in PPS pts, analyzing single domains and the global health status (GHS). EORTC-QLQ C30 and OV28 questionnaires were completed at screening and on Day 1 of every other treatment cycle (C) starting with C1, and at end of treatment (EoT). Comparisons are exploratory so no adjustments for multiplicity to control the overall Type I error rate were done.
Results: 214 pts had PPS ROC (PLD: 91/ T+P: 123 pts). Questionnaire completion was ~90% at baseline and well maintained up to 21 cycles (~83%). A median of 4 and 6 cycles of PLD and T+P were administered. The table shows the cross-sectional analysis of the mean score changes from baseline (MCB) of the functional, symptoms and GHS scales, including relevant findings at the corresponding timepoint.

Item/Domain	C3			C5			C7			C9		
	PLD	T+P	p[a]	PLD	T+P	p[a]	PLD	T+P	p[a]	PLD	T+P	p[a]
Appetite loss[1]	2.5	16.7	0.054	−1.4	7.0	0.975	−1.6	4.3	0.837	0	1.4	0.796
Dyspnea[1]	−1.3	4.3	0.024	1.4	5.0	0.195	−1.6	−0.7	0.750	−4.8	−2.9	0.932
Nausea/ Vomiting[1]	1.6	13.8	0.003	0.7	7.2	0.022	1.6	5.8	0.149	−1.2	6.9	0.114
Pain[1]	−3.4	−2.7	0.862	−0.4	−5.3	0.054	−1.6	−6.5	0.053	0	−8.3	0.053
Peripheral Neuropathy[1]	7.9	4.4	0.666	10.8	3.1	0.229	9.1	3.3	0.074	9.4	4.6	0.159
GHS/QoL[2]	−2.4	−6.6	0.352	−0.6	−3.1	0.909	0.9	−1.4	0.371	0.6	4.0	0.023

[1]Lower is better; [2]Higher is better; [a]T-test p-values comparing real scores.

Nausea/Vomiting favored PLD at C3 and C5, with a non significant trend across cycles. Meanwhile the pain scale favored T+P with improved results at C5 and beyond due to treatment.
Peripheral Neuropathy scale had a trend favoring T+P after 5 cycles, which was maintained.
In general the GHS scale had an important clinical difference in favor of T+P at C9, and was maintained for longer treated pts (EoT = MCB:PLD = −9.8, T+P = −3.4, p = 0.062).
Further findings will be discussed at the meeting.
Conclusions: Acknowledging the limitations of this analysis, differences were observed in different domains, characterizing the different profile of both treatments. The nausea/vomiting domain favored PLD, while T+P had better scores for pain and neuropathy, suggesting a non platinum/non-taxane treatment helps to recover from toxicities associated with prior therapies, which may offer new potential for following therapies. In general, addition of Trabectedin to PLD has no detriment in the global QoL and shows an improved outcome in the GHS for PPS ROC pts.

8030 POSTER

Phase II Study of NGR-hTNF Plus Doxorubicin in Relapsed Ovarian Cancer (OC)

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Background: NGR-hTNF consists of tumour necrosis factor fused with the peptide NGR, which selectively binds to a CD13 overexpressed on tumour blood vessels. NGR-hTNF is able to increase the intratumoral doxorubicin distribution by altering tumour vasculature.
Methods: OC patients failing at least one prior platinum-taxane line and with platinum-free interval either lower than 6 months (PFI <6) or between 6 to 12 months (PFI <12) received NGR-hTNF 0.8 $\mu g/m^2$ and doxorubicin 60 mg/m^2 on day 1 every 3 weeks. Doxorubicin was maintained up to 8 cycles and NGR-hTNF until disease progression. Primary endpoint was response rate. A 2-stage study design assumed that $\geqslant$2/17 and $\geqslant$6/37 patients with objective response would warrant further testing.
Results: Thirty-seven patients (25 with PFI <6; 12 with PFI <12) pretreated with 1 to 5 chemotherapy lines (median 1) were enrolled. Median age was 57 years (range 35−72) and 32 patients presented with a PS of 0. Median PFI was 4.6 months (95% CI 3.4−5.8).
Baseline CA125 ranged from 6 to 5,787 U/mL (median 549). Median baseline neutrophil-to-lymphocyte ratio (NLR), an index of systemic host immune response to tumour, was 2 (range 1−17). In total, 174 cycles were given (median 4; range 1−8). Neither increase of doxorubicin-related toxicities nor grade 3−4 NGR-hTNF related toxicity were registered.
Common grade 1−2 toxicity were transient chills (58%). After first study stage (n = 17), 6 patients showed partial response (2 with PFI <6; 4 with PFI <12) and the trial met its primary endpoint. After study completion (n = 37), a total of 17 patients had experienced stable disease (10 with PFI <6; 7 with PFI <12), yielding an overall disease control rate of 66% (92% in PFI <6; 48% in PFI <12). Median progression-free survival (PFS) was 4.9 months (95% CI 3.5−6.3) in overall population, 3.7 months in patients with PFI <6, and 8.2 months in patients with PFI <12. Moreover, median PFS was 7.8 vs 3.4 months (HR = 0.34; p = 0.01) in patients with baseline NLR lower or higher than the median value, respectively.
After a median follow-up of 10.8 months, 25 patients (68%) were still alive.
Conclusion: Tolerability and activity of NGR-hTNF plus doxorubicin deserve further randomized testing versus doxorubicin alone in platinum-resistant/refractory OC.

8031 POSTER

Prediction of Overall Survival (OS) Adjusted by Continuous Platinum-free Interval (PFI) at Fixed Timepoints in Patients With Recurrent Ovarian Cancer (ROC) − Results From OVA-301

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Background: OVA-301, a phase III study comparing trabectedin plus pegylated liposomal doxorubicin (PLD) *vs*. PLD alone in 672 patients progressing after one prior platinum-based regimen, showed significantly longer progression free survival and higher response rate for the combination, with acceptable tolerance (Monk et al; 2010). This study also showed longer OS in patients treated with the combination (Monk et al;