A randomized, phase III study (AGO-OVAR-9, GINECO-TCG, NSGO-OC-0102): gemcitabine-paclitaxel-carboplatin (TCG) versus paclitaxel-carboplatin (TC) as first-line treatment of ovarian cancer (OC): survival of FIGO stage I-IIA patients

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Background: One option to increase the efficacy of TC in pts with first diagnosis of ovarian cancer is to add a not cross-resistant drug.
Methods: We conducted a randomized, prospective, stratified, phase III study comparing therapy with TC to TC plus gemcitabine. From 7/02 to 4/04, pts with a histological verified first diagnosis of epithelial OC, FIGO IC-IV were randomized to either TC (paclitaxel [T] 175 mg/m^2 3h iv d1 + carboplatin [C] AUC 5 iv d1) or TCG (TC + gemcitabine [G] 800 mg/m^2 iv d1+8) for at least 6 cycles every 21 days starting within 6 weeks post-operatively. The randomization was balanced within three strata: 1) FIGO I-IIA, 2) FIGO IIB-IIIC with residual tumor ≤ 10mm, 3) FIGO IIB-IIIC with residual tumor > 10 mm or FIGO IV. Primary endpoint is overall survival.
Results: We enrolled 1,724 pts and administered 5,271 cycles TC and 5,130 cycles TCG. All baseline characteristics of the patients in both arms were well balanced. Most pts received 6+ cycles (87.2% TC, 86.3% TCG). Previous interim analyses have shown that TCG was tolerable but induced more hematological toxicity and that addition of gemcitabine did not improve overall survival in patients with FIGO stage IIB-IV disease. Approximately 11% of the patients had FIGO stage I-IIA disease. The late breaking abstract will report an analysis with a follow-up until end of January 2009 (median follow-up and range will be reported) including disease free survival and overall survival data in Stage I-IIA patients. Survival data for the two treatment arms will be compared using a log-rank test.
Conclusions: The final data will show if addition of G to TC provides any relevant benefit for patients with stage I-IIA ovarian cancer.