MONOTHERAPY VERSUS DOUBLE IN RESISTANT OVARIAN CANCER: A RANDOMISED PHASE II GINECO TRIAL (CARTAXHY)

Background: For ROC patients (pts) with early progression during or after (4-6 months) platinum and 3 weeks later use of single non-platinum agent (including wP) is standard (Kristensen G, et al. J Clin Oncol 2003; 21:5419). Few years later monotherapy has explored combination therapy.

Methods: Pts with ROC after a first or second line including a platinum and a taxane were randomized to receive wP (80 mg/m^2/week) in monotherapy with weekly topotecan (wT) or carboplatin (C) in combination. Secondary objectives included safety, quality of life, response rate (RR), overall survival (OS) and progression-free survival (PFS) from randomization.

Results:

**Study end-points**

- **Primary:** a comparison of progression-free survival (PFS) between single non-platinum agent (wP) and combination therapy (wP+wT and wP+C).
- **Secondary:** safety, quality of life, response rate (RR), overall survival (OS) and progression-free survival (PFS) from randomization.

**Criteria for eligibility**

- **Age:** >18 years.
- **Histologically proven epithelial ovarian cancer, primary carcinoma of the cervix or fallopian tube carcinoma.**
- **Performance status (PS):** 0-1.
- **ECOG performance status (PS):** 0-1.
- **EPO (U/ml):** 33.9 ± 74.5 ± 59.6.
- **Non-hematological toxicities:**
  - Grade 3-4 neutropenia (48 vs 13%), febrile neutropenia (24 vs 6%) were more frequent in combination therapy than in single agent arm and similar with wT or C combination. Vomiting (G3-4), peripheral motor neuropathy (G2-4) and hypersensitivity reaction (G2-4) were seen more frequently in the wP+C arm. Grade 3-4 hematological toxicities were more frequent in combination therapy (PNL 9%, PC 17% and T 18% vs 2%, 1% and 2% in the single agent arm and wP+wT, wP+C respectively). Median PFS of pts treated with single agent (312 days) was not significantly different from those treated with combination therapy (148 days vs 156 days). As was similar in wP+wT (135 days) and wP+C (146 days) arms.
- **Safety:** Combination therapy (CT) in platinum resistant ovarian cancer was found more toxic than weekly paclitaxel and the PFS advantage from CT was not statistically significant.

**Conclusions:** Combination therapy (CT) in platinum resistant ovarian cancer was found more toxic than weekly paclitaxel and the PFS advantage from CT was not statistically significant.