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Abstract title **AGO-OVAR 12: A RANDOMIZED PLACEBO-CONTROLLED GCIG/ENGOT-INTERGROUP PHASE III TRIAL WITH CHEMOTHERAPY +/- NINTEDANIB FOR ADVANCED OVARIAN CANCER: OVERALL SURVIVAL RESULTS**


**Aims**

**AGO-OVAR 12 study investigated the value of Nintedanib (N), an oral inhibitor of VEGFR, PDGFR, and FGFR in the treatment of newly diagnosed advanced ovarian cancer patients (pts). The data of final analysis of overall survival (OS) is reported here.**

**Method**

**Pts with FIGO IIB-IV ovarian cancer and upfront debulking surgery were randomly assigned (2:1) to receive six cycles of carboplatin (AUC 5 or 6) and paclitaxel (175 mg/m²) in addition to either 200 mg of Nintedanib (TC+N) or placebo (TC+Pl) twice daily for up to 120 weeks. Primary endpoint was investigator assessed progression-free survival (PFS) and has been reported to be significantly better previously. Here we report final results on overall survival (OS).**

**Results**

**1,366 patients were recruited 12/2009 – 7/2011 by 9 study groups; 911 TC+N and 455 received TC+Pl. Overall, 39% had a very high risk with FIGO III and residuals >1cm or FIGO IV while 61% had FIGO III and residuals ≤1cm or FIGO II (283 in TC-Pl, 556 in TC+N). After 605 observed deaths, OS did not show statistically significant differences (median N+TC 62.0 vs Pl+TC 62.8 months; HR 0.99; 95%CI:0.83 – 1.17; p=0.86). None of the subgroups defined by randomization strata, neither the high/low risk subgroups showed a statistically significant difference in OS between treatment groups. Adverse events leading to death occurred in 30 (3.3%) patients in TC+N and in 16 (3.6%) patients in TC+Pl.**

**Conclusion**

**Although well tolerated in combination with TC, Nintedanib in combination with TC did not affect OS compared to placebo.**



Keywords **ovarian cancer**

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