

**Abstract**

**tAnGo: A randomized phase III trial of  
gemcitabine (gem) in paclitaxel-containing,  
epirubicin/cyclophosphamide-based, adjuvant  
chemotherapy (CT) for women with early-stage  
breast cancer (EBC)**

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**Background:** After gem showed encouraging activity in advanced BC and pre-clinical evidence of a favorable interaction with paclitaxel, tAnGo was designed to evaluate, for the first time, its potential role in anthracycline and taxane containing adjuvant CT for EBC. **Methods:** tAnGo, an international phase III trial, compared EC-GT (4 cycles of epirubicin 90mg/m<sup>2</sup> IV and cyclophosphamide 600mg/m<sup>2</sup> IV day1 every (q) 3 weeks, followed by 4 cycles of paclitaxel 175mg/m<sup>2</sup>/3hour infusion day1 and gem 1,250mg/m<sup>2</sup> IV days1 and 8 q3 weeks) with EC-T, in respect of disease-free survival (DFS) in women with invasive higher risk EBC, with definite indication for adjuvant CT. Stratification was by country, age, radiotherapy, and nodal, estrogen (ER) & HER2 status. Toxicity, dose delivery and QoL, presented at ASCO'04 and SABCS'06, showed both regimens to be safe, feasible and tolerable. We

anticipated 550 DFS events at the preplanned primary endpoint efficacy analysis at 30 months (m) minimum follow-up (FU). **Results:** Between Aug'01-Nov'04, 3,152 patients were randomized from UK and Ireland, by 175 consultants from 127 centers; 1,576 EC-GT, 1,576 EC-T. Characteristics were balanced across treatments: 77% node positive (+ve), 55%  $\leq 50$  years old, 65% of tumors grade 3, 61%  $> 2\text{cm}$ , 41% ER -ve, 37% PgR -ve, 26% HER2 +ve (of 909 tumors assayed). This preplanned analysis with median FU of 35m (IQR 25–38m) identified 339 deaths and 548 DFS events. No significant difference between treatments is observed in DFS (HR=1.0 [95%CI 0.8–1.2] p=0.96) or overall survival (HR=1.1 [95%CI 0.9–1.4] p=0.35). Forest plots highlighted no subset where EC-GT was more effective, including a preplanned analysis by ER/PgR. **Conclusions:** The addition of gem at this dose and schedule confers no therapeutic advantage over EC-T for EBC.