

Final Results of a Randomized Controlled Phase III Trial (TAX 325) Comparing Docetaxel (T) Combined with Cisplatin (C) and 5-fluorouracil (F)

To CF in Patients (pts) with Metastatic Gastric Adenocarcinoma (MGC)

[4002]

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Background: Locally advanced or MGC has a poor prognosis (2-year survival 11.5%). Different treatments are used with no evidence of survival benefit.

Methods: Pts with chemotherapy-naïve MGC were randomized to either TCF: T 75 mg/m² day (d) 1, C 75 mg/m² d 1, and F 750 mg/m²/d continuous infusion (c.i.) d 1-5 every (q) 3 weeks (w) or CF: C 100 mg/m² d 1 and F 1000 mg/m²/d c.i. d 1-5 q 4 w. Pts with locally recurrent or metastatic gastric adenocarcinoma (including gastroesophageal junction in 22% pts) and

measurable/evaluable disease were eligible. Biased-coin randomization was stratified for center, liver metastases, prior gastrectomy, 5% weight loss, and measurability. Tumor assessments were performed q 8 w and externally reviewed. Time to progression (TTP) was the primary endpoint; the trial was equally powered for overall survival (OS).

Results: 457 pts (227/230 TCF/CF) were randomized between Nov 99-Jan 03. Median age was 55 yrs and 97% pts had metastatic cancer. Weight loss in prior 3 months [mo] was >5-10%: 29% pts and >10%: 27% pts.

TTP was longer with TCF (5.6 mo) compared to CF (3.7 mo; risk reduction 32%; log-rank p=0.0004). With median follow-up of 23 mo, OS was longer with TCF (risk reduction 23%, log-rank p=0.0201). 2-year survival was 18% with TCF vs 9% with CF. Response rate to TCF (37%) was superior to CF (25%; chi-square p=0.0106); 17%/31% pts had disease progression as best response to TCF/CF. Grade 3-4 treatment-emergent adverse events occurred in 81% and 75% of TCF and CF pts, the most common of which included diarrhea and stomatitis (20%/8% and 21%/27%

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Long Term Survival in Stage IIIb Non-small Cell Lung Cancer (NSCLC)

Treated with Consolidation Docetaxel Following Concurrent Chemoradiotherapy (SWOG S9504)

[7059]

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Background: The optimal approach to chemoradiotherapy for unresectable stage III NSCLC remains unclear. We have previously reported the efficacy of consolidation docetaxel (D) following concurrent cisplatin-etoposide (PE) and thoracic radiotherapy (RT) in stage IIIb NSCLC in which documentation of T4 (non-effusion) or N3 status was required (S9504).

Methods: Here we update results in regard to survival at 5 years in 83 patients (pts) treated with P: 50 mg/m² days 1, 8, 29 and 36, E: 50 mg/m² days 1-5 and 29-33 and concurrent thoracic RT starting day 1: 61 Gy (1.8-2.0 Gy/day), followed by consolidation docetaxel 75-100 mg/m² every 21 days for 3 cycles.

Results: median age 60 (34-80), male/female: 61/22, performance status:

	Median Survival (months)	3 Yrs.	4 Yrs.	5 Yrs.
PE/RT → D (S9504)	26 (CI 18-430)	40% (CI 24-55)	29% (CI 19-29)	29% (CI 19-29)
PE/RT → PE (S9019)	15 (CI 10-22)	17% (CI 7-27)	17% (CI 6-28)	17% (CI 6-28)

0-1/2:78/5, TNM: T4N0-1: 31, T4N2: 22, N3: 30. Median follow-up: 71 months (mos). Median progression-free survival (PFS): 16 mos. Median survival (MST): 26 mos. 5 year survival: 29%. MST and 5 year survival for Stage IIIb subsets: T4N0-1: 32 mos and 29%; T4N2: 26 mos and 37%; N3: 16 mos and 20%. Survival data are compared below to SWOG 9019, which treated a similarly staged IIIb cohort of 50 pts with identical concurrent chemoradiotherapy, differing only in substitution of consolidation docetaxel for continued PE.

Conclusions: 1) Long term survival endpoints achieved in S9504 in documented Stage IIIb NSCLC compare favorably with the SWOG historical control (S9019) and other published series in this pt population. 2) 5 year survival of stage IIIb subsets ranges from 20-37%. 3) Ongoing intergroup trial S0023 is further evaluating the S9504 regimen followed by maintenance therapy with the EGFR inhibitor gefitinib or placebo (Supported by CA 30102). ●