

Phase III study of maintenance gemcitabine (G) and best supportive care (BSC) versus BSC, following standard combination therapy with gemcitabine-carboplatin (G-Cb) for patients with advanced non-small cell lung cancer (NSCLC).

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Abstract:

Background: The use of single agent cytotoxic or targeted agent as maintenance following combination therapy represents a useful strategy to improve patient outcomes in advanced stage NSCLC. An earlier study with gemcitabine as maintenance therapy demonstrated improved time to progression (TTP) compared to BSC (6.6 mos. vs 5.0 mos., $p < 0.001$) (Brodowicz et al, *Lung Cancer*, 2006; 52:155-163). Based on this, we conducted a randomized phase III study to compare G + BSC versus BSC as maintenance therapy for patients with advanced NSCLC. **Methods:** Patients with stage IIIB (wet)/IV NSCLC were initially treated with gemcitabine (1,000 mg/m² on day 1 and 8) and carboplatin (AUC = 5 mg/mL.min on d 1) every 3 weeks for 4 cycles. Subsequently, patients with CR/PR or SD were randomized 1:1 to receive maintenance G (1,000 mg/m² on d 1 and 8), every 3 weeks with BSC or BSC alone until disease progression. The primary endpoint was the comparison of overall survival between the two arms and the secondary endpoint was progression free survival (PFS). **Results:** 519 patients were enrolled (median age-67 years, stage IV disease- 86%, ECOG performance status 0/1-75%). With G-Cb, the RR was 28% (CR-1.2%, PR-26.8%), and 37% had SD. Following 4 cycles of G-Cb, 255 non- progressors were randomized to receive G + BSC (n = 128) or BSC (n = 127). The median PFS was 3.9 m (95% CI:3.3, 5.6) for G + BSC and 3.8 m (95% CI: 2.6, 5.5) for BSC. Median survival was 8.0 m (95% CI: 6.0, 10.2) for G+ BSC and 9.3 m (95% CI: 7.7, 12.7) for BSC. The differences in survival between the two arms were not statistically significant (HR = 0.97 [95% CI: 0.72, 1.30], $p = 0.84$). Maintenance therapy was tolerated well despite a higher incidence of grade 3/4 toxicity (anemia 9.4% vs. 2.4%; neutropenia 13.3% vs. 1.6%; thrombocytopenia 9.4% vs. 1.4%; and fatigue 3.9% vs. 1.6%). **Conclusions:** The use of gemcitabine as maintenance therapy failed to improve survival following G-Cb in patients with advanced NSCLC.