A prospective, single-arm, phase I/II trial of RAS peptide vaccine TG01/GM-CSF and gemcitabine as adjuvant therapy for patients with resected pancreatic adenocarcinoma

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Background

Recent clinical studies have demonstrated the need for improved adjuvant therapies in pancreatic adenocarcinoma. The ongoing phase III trial of gemcitabine plus nab-paclitaxel versus gemcitabine in patients with resected pancreatic cancer has demonstrated a substantial increase in overall survival compared with gemcitabine alone.6

Methods

Eligible patients were randomized 2:1 to receive 6 cycles of gemcitabine 1000mg/m² and 6 cycles of gemcitabine 1000mg/m² plus 720μg/m² of recombinant human granulocyte macrophage colony-stimulating factor (rhGM-CSF). The combination arm also received 720μg/m² of rhGM-CSF.8 A recommended dose of gemcitabine was determined based on the results of this phase II trial.9

Results

The primary endpoint of this phase II trial was the median overall survival of patients receiving gemcitabine monotherapy versus those receiving gemcitabine plus rhGM-CSF. The median overall survival was significantly longer in the combination arm compared with the monotherapy arm (11.9 vs 8.6 months; hazard ratio, 0.66; 95% CI, 0.46 to 0.96; P = 0.03).10

Conclusions

These results support the use of combination therapy with gemcitabine and rhGM-CSF as a potential adjuvant strategy for patients with resected pancreatic cancer. Further studies are needed to confirm these findings in a larger, randomized clinical trial.