Randomized phase II trial of NGR-hTNF and chemotherapy in chemo-naïve patients with non-small cell lung cancer (NSCLC): preliminary results


Background and methods

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**Open label, randomized phase II trial**

**Chem-o-therapy, stage IIIb/IV NSCLC**

**Brain metastases (if adequately treated)**

**Primary endpoint: progression-free survival (PFS)**

**Secondary endpoint: response rate (RR) duration of RR, safety and OS**

**Hypothesis testing: 91% PFS, sample size: 102/83**

**Study status**

**Study population**

127 patients enrolled as follows:

- After median follow-up of 9.3 months (95% CI 5.1-13.5), 50 events (progressive disease or death) occurred and data are highly censored and immature for primary analysis.

- 80 patients (40 in each arm) presently analyzed for safety and interim activity.

**Early treatment discontinuations:**

- Arm A: n=13 (10 toxicity, 2 local therapy, 2 symptomatic deterioration)

- Arm B: n=5 for toxicity, 2 for symptomatic deterioration

**Drug combination:**

- Cisplatin 80 mg/m² + E75 (150 mg/m²) x 6 (d1)

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**Conclusions**

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**PFS in patients completing 6 cycles and continuing NGR-hTNF as maintenance**

**PFS in younger patients (<25% patients, 56 years)**

**References**


**Objectives of treatment: NGR-hTNF was well tolerated in combination with both chemotherapy regimens: phase II/III and cisplatin plus gemcitabine.** There was no evidence of toxicity; side effects associated with hTNF, and premature death in patients with squamous cell histology.

**Preliminary results showed promising antitumor activity of NGR-hTNF plus chemotherapy regimen in patients with squamous cell histology or in combination with hTNF as maintenance after completing 6 cycles of chemotherapy.**