Phase II trial of NGR-hTNF and doxorubicin in relapsed small-cell lung cancer (SCLC)

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Background and methods

NGR-hTNF: a human Tumour Necrosis Factor (hTNF) 8-mer peptide administered by pegylation and complexing with doxorubicin for intravenous delivery.

The combination of NGR-hTNF and doxorubicin can be safely administered in relapsed SCLC patients.

NGR-hTNF plus doxorubicin showed evidence of activity, which was weakly correlated with prior platinum sensitivity.

Further development of this combination is warranted.

Results

Non-hematological AEs (≥15% of patients) by platinum dose

In patients with partial response (n=6): 6.3 months
In patients with stable disease (n=15): 1.0 months
In patients with disease control (n=15): 4.6 months

Safety

- Non-hematological AEs (>15% of patients)
  - Hematological AEs (<15% of patients)

- Grade 3–4 hematological AEs: neutropenia (NGR-hTNF 14%, doxorubicin 15%), anemia (NGR-hTNF 8%, doxorubicin 15%), thrombocytopenia (NGR-hTNF 3%, doxorubicin 15%).

- Grade 3–4 non-hematological AEs: fatigue (NGR-hTNF 14%, doxorubicin 15%), nausea (NGR-hTNF 14%, doxorubicin 15%), vomiting (NGR-hTNF 8%, doxorubicin 15%), constipation (NGR-hTNF 8%, doxorubicin 15%).

- No grade 5 toxicity was reported.

Conclusions

Best response by platinum-sensitivity

- Overall survival
  - Median PFS: 6 months survival rate: 48% 1-year survival rate: 24%

- OS by neutrophil-to-lymphocyte ratio (NLR)
  - No effect of NLR on OS
  - In PR patients with NLR ≤ (p=0.01): 8.4
  - In PS patients with NLR ≤ (p=0.08): 7.5

- OS with platinum-resistant (PFS): 6.6 months

- OS with platinum-sensitive: 9.6 months

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