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A Phase II Clinical Trial of Nivolumab and Temozolomide for Neuroendocrine Neoplasms (NEN): Updated overall survival data

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BACKGROUND

Treatment options are limited in patients with metastatic neuroendocrine neoplasms (NEN). Combination temozolomide and nivolumab showed encouraging objective response rates of 35.7% in advanced NEN regardless of site of origin, with response rates of 64% in lung NEN and 67% in pancreatic NEN (NCT03728361). We present updated survival data on follow-up from a phase II trial of combination nivolumab and temozolomide in patients with advanced NEN.

METHODS

NCT03728361 is a nonrandomized, phase II study of nivolumab and temozolomide in patients with NEN. Any patient with disease progression in the prior 12 months was eligible for enrolment, irrespective of line of therapy. The primary endpoint was response rate using RECIST 1.1. Secondary endpoints included progression-free survival (PFS), overall survival (OS), and safety. OS was estimated using Kaplan – Meier method with median and 95% CI. The survival curves were compared using log-rank test. OS was defined as survival from the start of treatment to death. Patients alive were censored at the last follow-up.

RESULTS

After a median follow-up of 35.8 months (range: 3 – 52.7 months), the median OS was 38.6 months for the entire cohort of 28 patients with NEN (95% CI: 20.7 months - Not Reached (NR)). When classified by site of origin, median overall survival in lung NEN was 38.6 months (95% CI: 8.8-NR), pancreatic NEN was NR (95% CI: 32.3 -NR), and NEN not of lung or pancreatic origin was NR (95% CI: 16.8 months-NR). The difference in OS amongst each of these sites was not statistically significant (p=0.779).

CONCLUSIONS

The combination of nivolumab and temozolomide demonstrated promising activity in lung and pancreatic NEN. Cohorts were of small sample size thereby limiting generalizability. Comparison with historical controls will require further maturation of survival data. Future randomized studies of the combination in this population are warranted.

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