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Pembrolizumab for the Treatment of Recurrent High Grade Neuroendocrine Neoplasms

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BACKGROUND

High-grade neuroendocrine neoplasms (HG-NENs) are a heterogenous and biologically aggressive rare subset of NENs. Few therapeutic options are available to metastatic HG-NENs. To date, first line treatment is platinum- or temozolomide-based chemotherapy which provide modest benefits in overall survival (OS) and progression free survival (PFS). Given the promising activity of immunotherapy across several cancer types, our center initiated a phase II trial of pembrolizumab monotherapy in HG-NENs.

METHODS

This was an open label, non-randomized phase II study in patients with metastatic extra-pulmonary HG-NEN, Ki67 >20%, treated with pembrolizumab following progression on platinum- or temozolomide-based chemotherapy. Primary endpoint was overall response rate (ORR) as measured by irRECIST. Secondary endpoints included clinical benefit rate (CBR), OS, and PFS.

RESULTS

Between December 2017 and December 2018, 6 patients (5 females/1 male) with HG-NEN were enrolled and received at least 1 dose of pembrolizumab. Histology was characterized as poorly differentiated in 50% and well-differentiated in 50%. Ki-67 ranged from 25% to >90%. The majority of patients had primary tumors originating from the rectum (33%), pancreas (16.7%), or liver (16.7%). One patient with small cell cancer of the prostate and one with neuroendocrine breast carcinoma (NEBC) were also included. One patient (16.7%) had stable disease that was maintained for 8.3 months. The remaining 5 (83.3%) patients had progression of disease (POD) by irRECIST at 6 weeks. The ORR was 0% with CBR of 16.7%. Pembrolizumab was well tolerated with 1 grade 3 event and 1 grade 4 event considered to be potentially drug-related.

CONCLUSIONS

Pembrolizumab has limited activity as monotherapy in HG-NENs. One patient with NEBC had stable disease for 8.3 months. These findings are consistent with prior publications assessing pembrolizumab in metastatic grade 3 NENs.

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