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Exploring Real World Outcomes of Ipilimumab and Nivolumab in Patients with Metastatic Gastroenteropancreatic Neuroendocrine Carcinoma (GEP-NEC)

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BACKGROUND: Dual blockade of immune checkpoints (ICPIs) using ipilimumab and nivolumab has improved outcomes in patients with refractory high-grade neuroendocrine neoplasms (NENs) in phase II clinical trials (DART SWOG 1609 and CA209). There was no adequate description of the tumor differentiation (high-grade well-differentiated neuroendocrine tumor vs poorly differentiated NEC). Our study aims to report the effectiveness and toxicity profile of dual ICPIs in a real world GEP-NEC patient population.

METHODS: Data on metastatic GEP-NEC patients treated with either ICPIs (single and dual ICPIs) or chemotherapy in the second line setting were retrieved from three cancer centers (Seidman , Vanderbilt-Ingram, and Fox Chase Cancer Centers). Associations between treatment characteristics and outcomes, including progression free survival (PFS) and overall survival (OS), were evaluated.

RESULTS: 70 patients (2007-2020) with metastatic GEP-NEC, of whom 41 patients (22 males, 19 females, median age 62 years old) were eligible for the final analysis. All patients were refractory to platinum etoposide in the first line setting. The median PFS for patients who received dual ICPIs (11 patients), single agent ICPI (8 patients), and cytotoxic chemotherapy (19 patients) were 258 days, 56.5 days, and 47 days, respectively (p=0.0001). Median overall survival (OS) for those groups were not reached (NR), 18.7 months, and 10.5 months, respectively

(p=0.004). There were no significant differences in treatment outcomes in patients according to tumor mismatch repair (MMR) or tumor mutational burden (TMB) status. Grade 3-4 adverse events (AEs) were reported in 11.1% of the patients who received dual ICPIs, however none of these AEs led to permanent treatment discontinuation.

CONCLUSION: In the second line setting, patients with GEP-NECs treated with dual ICPIs (ipilimumab and nivolumab) experienced improved PFS and OS compared to patients treated with single agent ICPI or cytotoxic chemotherapy. These results need to be validated in future prospective studies.

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