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Safety in Patients With Neuroendocrine Tumors Receiving Telotristat Ethyl (TE) With Peptide Receptor Radionuclide Therapy (PRRT)

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BACKGROUND: Telotristat ethyl (TE) is an oral tryptophan-hydroxylase inhibitor approved to treat carcinoid syndrome diarrhea (CSD) in combination with somatostatin analogues (SSAs) in adults with CSD inadequately controlled with SSAs alone.

METHODS: Patients who completed Phase 2 or Phase 3 trials (NCT00853047, NCT01104415, NCT01677910, NCT02063659) of TE for CSD were eligible for this analysis if they received concomitant PRRT. We examined treatment-emergent serious adverse events (TESAEs) and elevations in hepatic enzymes relative to the start date of PRRT.

RESULTS: Data from 24 patients (16M/8F, median age 64 years [range 39–78]) who received TE and PRRT were included. Twelve patients experienced 17 SAEs within 180 days of starting PRRT. Six patients experienced disease progression 1–78 days after starting PRRT. The remaining SAEs were: carcinoid crisis (Day [D] 2), vomiting (D2), pyrexia (D19), sciatica (D27), bowel obstruction (D28), elective hospitalization for PRRT (D76), face wound (D93), sleep apnea (D118), bowel obstruction (D137), syncope (D137), and septicemia (D179). All events were unrelated to treatment. Two patients experienced adverse events of special interest of hepatic enzymes increased (D380 and D399), 1 moderate and 1 serious, the latter led to study discontinuation.

CONCLUSION: An analysis of safety data from 24 patients who received concomitant TE and PRRT in the TE clinical program suggests a profile consistent with the known safety profiles of each of the approved therapies.

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