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COMPOSE: Pivotal Phase III Trial for Well-Differentiated Aggressive Grade 2/3 Gastroenteropancreatic Neuroendocrine Tumors Comparing ¹⁷⁷Lu-edotreotide with Best Standard of Care

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BACKGROUND

Gastroenteropancreatic neuroendocrine tumors (GEP-NETs), which frequently develop metastatic disease, represent an estimated 70% of NETs. There are limited treatment options with current standard therapies for well-differentiated aggressive grade 2 and grade 3 (Ki-67 index 15–55%) GEP-NETs; however, these may include somatostatin analogues; peptide receptor radionuclide therapy (PRRT); molecular targeted therapies (everolimus or sunitinib); chemotherapy; and cytoreductive procedures. PRRT, which uses radiolabeled somatostatin analogues to selectively target somatostatin receptor expressing tumor cells, may stabilize disease and induce objective tumor responses. The radiolabeled somatostatin analogue ¹⁷⁷Lu-edotreotide has demonstrated promising efficacy and a favorable safety profile. Retrospective data in metastatic GEP-NETs treated with two or more ¹⁷⁷Lu-edotreotide cycles demonstrated nearly 30 months progression free survival (PFS). COMPOSE (NCT04919226), a prospective, randomized, controlled, open-label, multi-center Phase III study, aims to extend therapeutic options for patients with well-differentiated aggressive grade 2 and grade 3, SSTR+, GEP-NETs.

METHODS

COMPOSE evaluates efficacy, safety, and patient-reported outcomes of first- or second-line treatment with ¹⁷⁷Lu-edotreotide PRRT. At least 202 patients with somatostatin receptor-positive (SSTR+) disease will be randomized 1:1 to up to six cycles of ¹⁷⁷Lu-edotreotide, given at 6- to 8-week intervals, or to an active comparator (either chemotherapy [CAPTEM or FOLFOX] or everolimus, according to investigator's choice). PFS, the primary endpoint, will be assessed every 12 weeks until disease progression (RECIST v1.1) or death, whichever occurs earlier. Overall survival, assessed up to 2 years after disease progression, is a secondary outcome.

RESULTS

COMPOSE recruitment commenced in September 2021 and currently includes 29 open sites in Australia, France, India, Italy, the Netherlands, Spain, Sweden, the United Kingdom, and the United States. More sites and countries will follow.

CONCLUSIONS

COMPOSE results are expected to inform about optimal treatment options for patients with well-differentiated aggressive grade 2 and grade 3 SSTR+ GEP-NETs, including for first-line therapy.

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