COMPOSE: Pivotal phase III trial to compare ^{177}Lu-edotreotide with best standard of care for well-differentiated aggressive grade 2 and 3 gastroenteropancreatic neuroendocrine tumours

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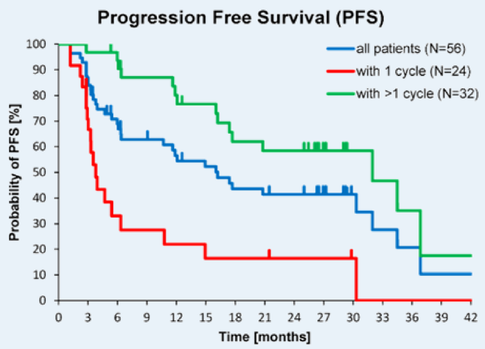
Background

Approximately 70% of neuroendocrine tumours are gastroenteropancreatic (GEP-NETs). These frequently develop metastatic disease with limited treatment options.[1]

For well-differentiated high grade 2 and 3 GEP-NETs, current therapies include peptide receptor radionuclide therapy (PRRT), somatostatin analogues, chemotherapy, cytoreduction and molecular targeted therapies (everolimus, sunitinib) with no specified use sequence.

PRRT uses radiolabelled somatostatin analogues to selectively target somatostatin receptor expressing (SSTR+) tumour cells. Use may stabilise disease and induce objective tumour response.[2]

Figure 1. *Kaplan-Meier estimates of progression free survival in the study population depending on number of no-carrier added ^{177}Lu-edotreotide PRRT cycles[3]*



^{177}Lu edotreotide is an innovative radiolabelled somatostatin analogue with promising efficacy and a favourable safety profile.[2,3] Retrospective data in metastatic GEP-NETs treated with ≥2 cycles of ^{177}Lu-edotreotide demonstrate progression free survival (PFS) of ≥30 months (Figure 1).[3]

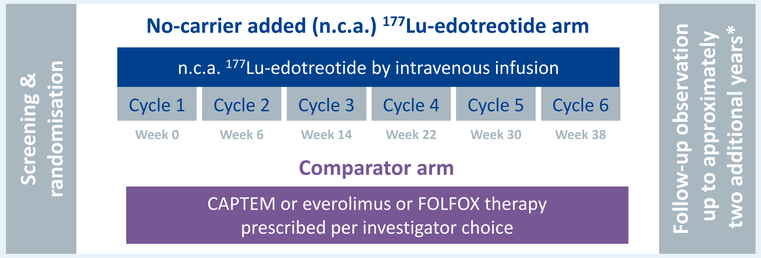
The Phase III COMPETE trial, which has completed patient recruitment, is comparing ^{177}Lu edotreotide efficacy/safety versus everolimus in grade 1 and 2 GEP-NETs.[4]

Trial design

COMPOSE is a prospective, randomised, controlled, open-label, multi-center Phase III trial recruiting patients with well-differentiated aggressive grade 2 and 3 (Ki-67 index 15–55%), SSTR+, GEP-NETs.

COMPOSE will evaluate efficacy, safety and patient-reported outcomes of 1st- or 2nd-line treatment with ^{177}Lu edotreotide PRRT compared to best standard of care [investigator´s choice of chemotherapy (capecitabine-temozolomide: CAPTEM or folinic acid, fluorouracil and oxaliplatin: FOLFOX) or everolimus] (Figure 2).

Figure 2. *Summary schedule of treatments and follow-up consultation*



*Treatment response, tumour progression, survival data, information on further antineoplastic treatments and secondary malignancies

COMPOSE aims to randomize 202 patients 1:1 to a defined number of cycles ^{177}Lu-edotreotide or an active comparator (Figure 2).

Primary endpoint

- Progression free survival, assessed every 12 weeks until disease progression (response evaluation criteria in solid tumors v1.1) or death, whichever occurs earlier

Key secondary endpoint

- Overall survival, assessed up to 2 years after disease progression

Current status

- Recruitment has opened in several countries with approximately 40 specialist centres in 10 countries scheduled to be open

COMPOSE results are expected to increase treatment options for patients with well-differentiated aggressive grade 2 and 3 GEP-NETs, including for 1st-line therapy

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Clinical Phase III Trial COMPOSE
NCT04919226: ClinicalTrials.gov

Find more trial information on
www.itm-gep-net-trials.com

Conflicts of interest: Co-authors participated in the trial as Principal Investigators
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