

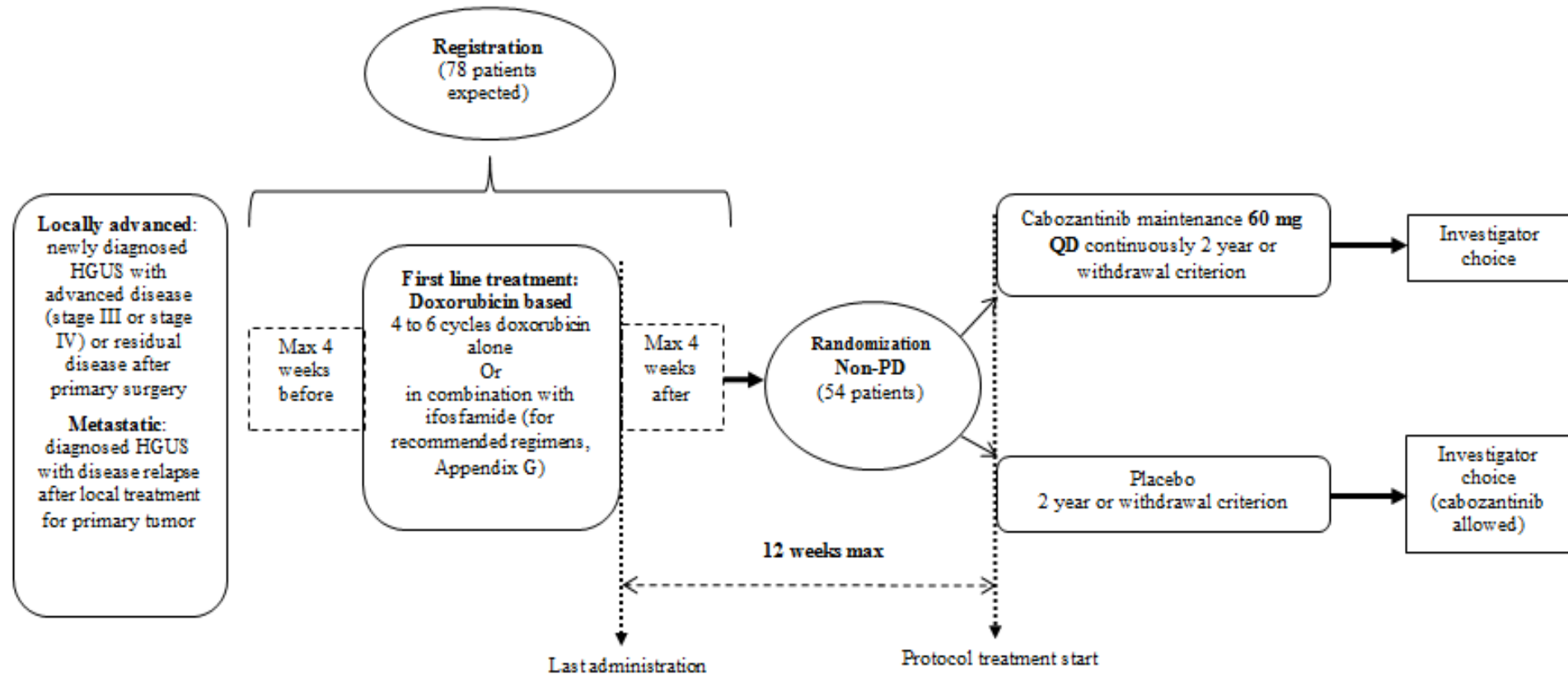
EORTC 62113-55115

A randomized double-blind phase II study evaluating the role of maintenance therapy with cabozantinib in High Grade Undifferentiated Uterine Sarcoma (HGUS) after stabilization or response to doxorubicin +/- ifosfamide following surgery or in metastatic first line treatment

EORTC SC: Isabelle Ray-Coquard (STBSG)
Nick Reed (GCG)

Study design

Late Phase II study



1° endpoint: PFS rate at 4 months from randomization

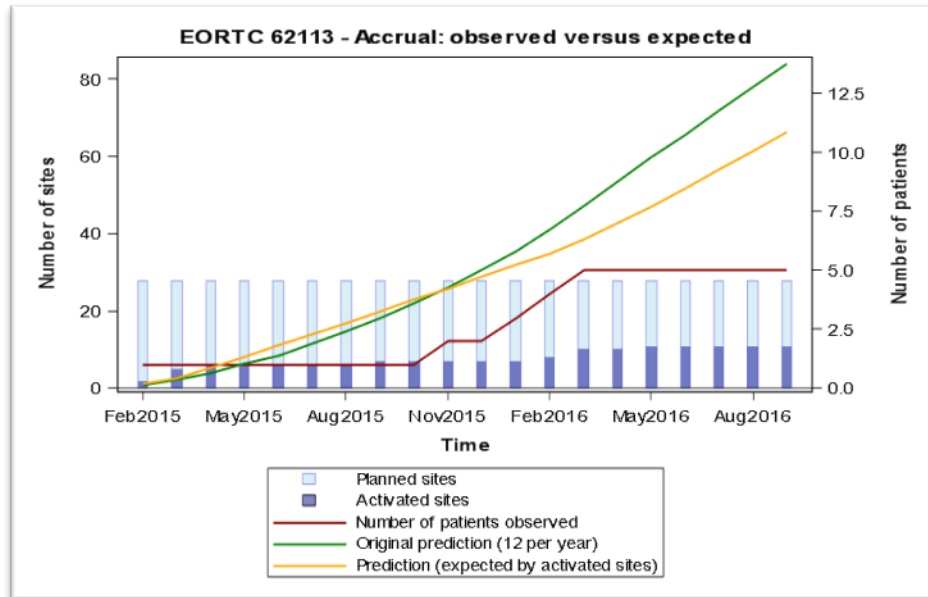
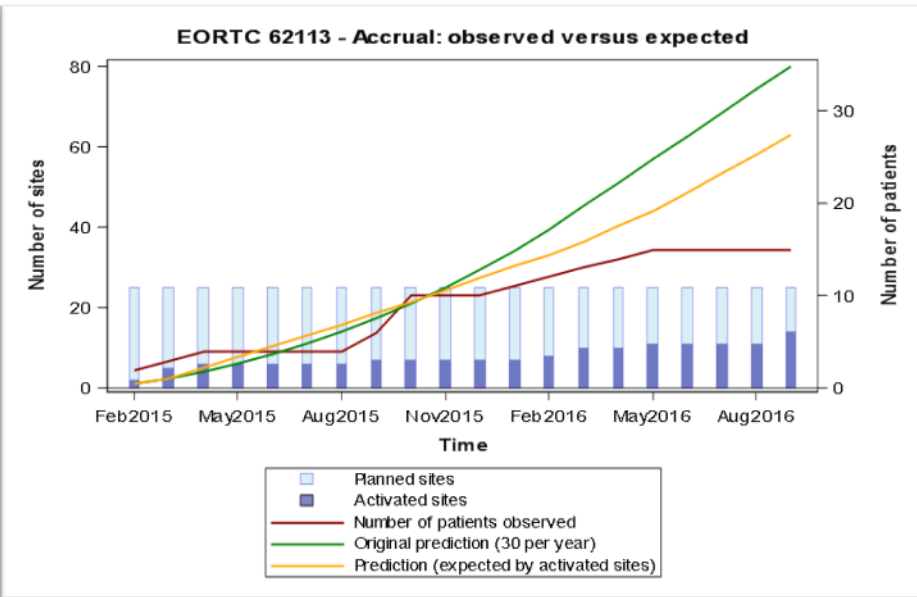
2° endpoints: PFS, OS, RR and duration of response (RECIST 1.1), QoL (QLQ-C30 + QLQ-EN24), Toxicity (CTCAE 4.0)

Study accrual

(Cut-off date: 16/09/2016)

Registrations

Randomizations



Institution	Total nb of patients registered	Total nb of patients randomized
227.Centre Leon Berard (FR)	9	3
235.Centre R.Gauducheau (FR)	2	
117.U.Z. Antwerpen (BE)	1	
342.Amc Amsterdam (NL)	1	1
366.Hosp Univ San Carlos (ES)	1	1
632.Addenbrookes Hosp (GB)	1	
Total	15	5

Special issues (ctd)

- **EORTC study status**

A **scientific amendment** to the protocol is under finalization by the study team at EORTC and the Study Coordinators which includes:

- High-Grade Endometrial Stromal Sarcoma patients are allowed to participate in the study
- High grade Leiomyosarcoma are allowed to participate in the study
- Timing of registration/randomization:
 - Patients can be registered no earlier than 4 weeks prior to start of the 1st line treatment and no later than 4 weeks after last administration of 1st line treatment.
 - Patients can be randomized within 12 weeks after last administration of 1st line treatment, before the start of protocol treatment
 - Updated language in the protocol and PISIC according to the version 11.0 and 12.0 of the Cabozantinib Investigator's Brochure

Special issues (ctd)

- **Status of activation of the collaborative groups**

NCRI (UK):

Approvals of this study have been received from the Competent Authorities and Central EC in UK. Two out of 11 sites have been authorized for patient recruitment:

- Cambridge University Hospital (Site 632; Dr. Helena Earl)
- Beatson West of Scotland Cancer Centre (Site 6982; Dr. Nicholas Reed)

NRG Oncology (US):

Study concept/LOI has been submitted to CTEP NCI in the summer of 2015 and together with EORTC, Dr Martee Hensley (NRG Oncology Study Coordinator) has prepared and submitted a reply to CTEP's comments in February 2016. In April 2016, Dr Hensley informed EORTC that CTEP has provided conditional approval to enroll a maximum of 20 patients from NRG Oncology. The absolute deadline to open the first US site is 8 October 2016. Discussions between EORTC, CTEP and NRG Oncology are ongoing for the set-up of the participation of US sites.