NRG
NCRI

Ongoing Trials – status update

EORTC – STBSG-GCG
Study 62113-55115

Trial setting: Advanced or metastatic Uterine Sarcoma (High grade) after SD or RC/RP to 1st line doxorubicin based CT

Study Design: randomized phase II

Sponsor(s): EORTC via IRCI initiative

Planned No. of patients: 90 registered, 54 randomized

Current accrual: 18 registered, 5 randomized

Other important information:

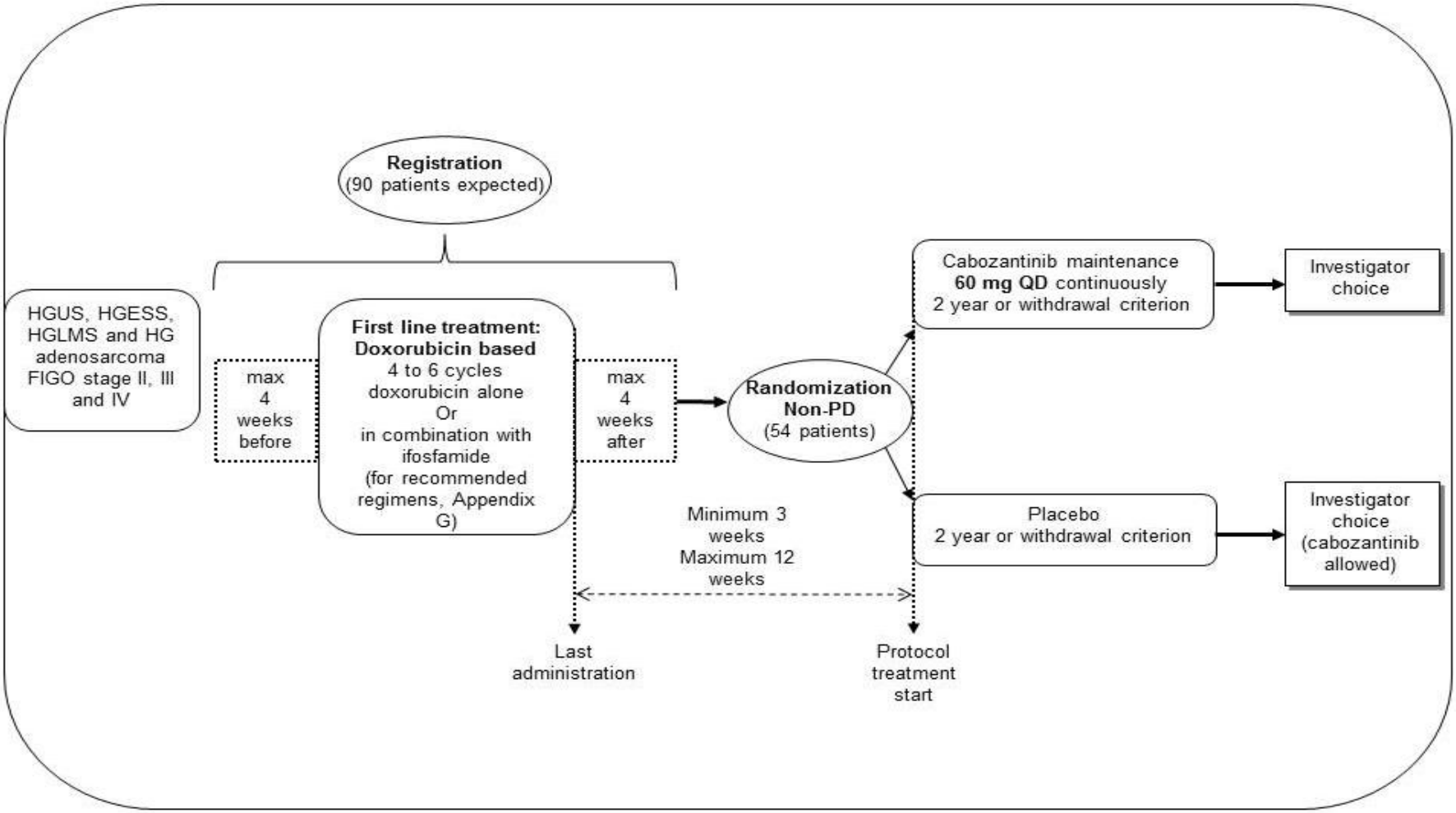
- NRG not able to participate (supplying drug via Exelesis conflicting),
- new amendment to open the inclusion to all high grade uterine sarcoma (including LMS, adenosarcoma and HG ESS)

EORTC – STBSG-GCG
Study 62113-55115:
A randomized double-blind phase II study evaluating the role of maintenance therapy with cabozantinib in High Grade Uterine Sarcoma (HGUtS) after stabilization or response to doxorubicin +/- ifosfamide following surgery or in metastatic first line treatment

SC: Nick Reed , NHS Greater Glasgow & Clyde, UK (GCG)

SC: Isabelle Ray-Coquard , Centre Leon Berard, France (STBSG)

Study design



Main eligibility criteria

- At registration:
  - Patients who are suitable for treatment with doxorubicin +/- ifosfamide and fall within one of the following patient populations:

    HGUS, HGESS, HGLMS and HG adenosarcoma
- At randomization:
  - Central pathological confirmation: Histological evidence of HGUS, HGESS, HGLMS and HG adenosarcoma
  - Non-progressive patients (CR, PR, SD) after first line treatment (standard chemotherapy consisting of 4 to 6 cycles of doxorubicin alone or in combination with ifosfamide) and at time of randomization
  - The subject's organ, marrow function and laboratory values need to be within the defined ranges before randomization

Endpoints

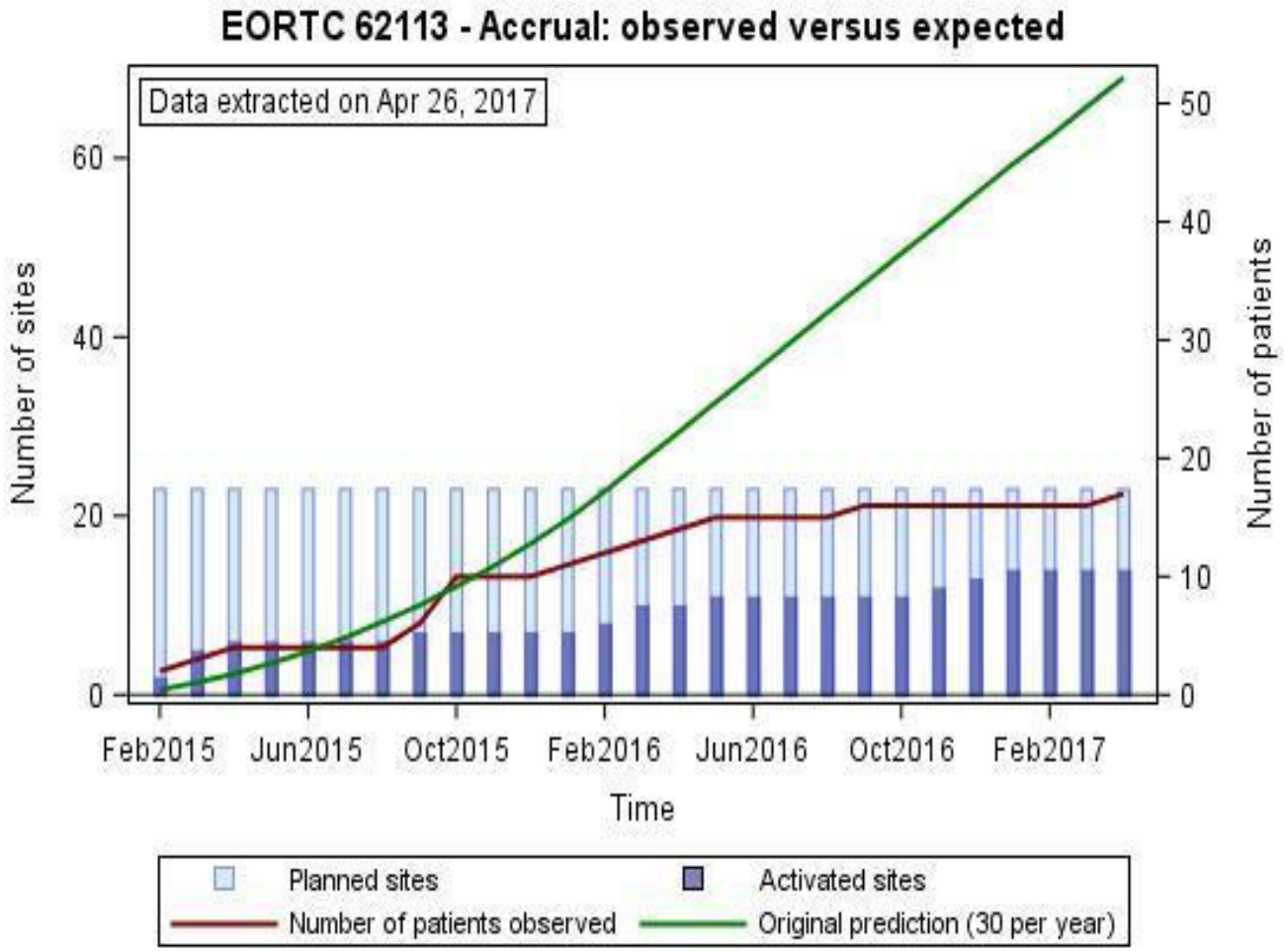
Primary endpoint

- PFS rate at 4 months

Secondary endpoints

- PFS (RECIST 1.1)
- OS
- Response rate and duration of response to cabozantinib (RECIST 1.1)
- Response rate to doxorubicin-based chemotherapy after registration
- HRQoL (QLQ-C30 + QLQ-EN24)
- Safety profile of maintenance therapy & at cross-over

Accrual: Registration



Accrual per institution (as of 11/05/2017)

Institution	# Registered	# Randomized
Centre Leon Berard (227)	10	3
Institut de Cancerologie de l'Ouest (ICO) - Centre Rene Gauducheau (235)	3	0
Academisch Medisch Centrum - Universiteit van Amsterdam (342)	1	1
Hospital Universitario San Carlos (366)	1	1
Cambridge University Hospital NHS - Addenbrookes Hospital (632)	1	0
Universitair Ziekenhuis Antwerpen (117)	1	0
Greater Glasgow and Clyde - Beatson West of Scotland Cancer Centre (6982)	1	0
Total	**18**	**5**

Other authorized institutions did not yet register a patient.
Target accrual = 54 randomized patients

Accrual per group (as of 11/05/2017)

Group	# Registered	# Randomized
EORTC STBSG/GCG	16	5
NCRI	2	0
Total	**18**	**5**

Reason of screening failure	# failures
No central pathological confirmation of disease	4
Patient refusal	2
Inadequate organ or marrow function or lab values	1
Randomization outside allowed time window	1
Progression during first line treatment	2
Patient condition deteriorated during first line treatment	1
Total	**11**