RARE TUMOURS Committee
Tuesday, Nov.10, 2015, 4:00pm – 6:00pm
5F Room, Jikei University, Tokyo

Chair: I. Ray-Coquard Co-Chair: J. Ledermann
Harmonization liaisons: B.Votan/J.Bryce (Ops), BH Nam/J.Paul (Stats)

AGENDA

- **Call to Order and Welcome (COI declarations)**
- **Review/Approval of Minutes/Report of meeting: May 2015**

1. Update on the GCIG consensus review (including pub. and summary of brainstorming event) 10 min
Smartphone application for GCIG guidelines

2. On-going clinical trials:

Update on Alienor trial: Ray-Coquard

3. New proposals:

New project on first line CCCov	**M McCormack & L Farrelly**
New project for germ cell tumors KGOG	**JY Park**
Project carcinosarcoma	**M Wilson (PMHC)**
Registry for SCC, next steps	**Ray-Coquard/ J Ledermann**

4. Future Directions: all

Adjourn

1. GCIG recommendations & RTWG meeting London Nov. 2013

- **Publications :**
  - **Proposal from ESGO : One chapter dedicated to GCIG guidelines for rare tumors in the textbook**
    - **Authors : 20 coordinators + Chair of GCIG in 2013**
    - **Draft circulated next week**

- **IJGC agree for the open access**
- **Smartphone application dedicated to GCIG reviews (to discuss with the GCIG webmaster)**

2. On going clinical trials

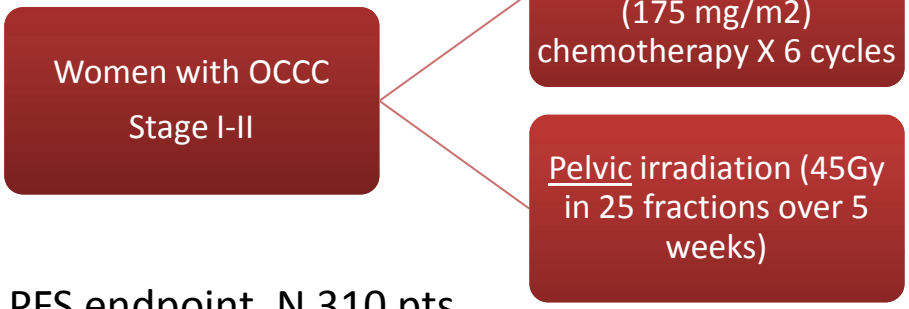
- CCC (Ov & Ut)
  - NICC trial (Scottish Group) relapse less than 6 months Mono CT vs. Nintenanib
  - 6/ 90 pts already included
- HGUS
  - EORTC/IRCI 62113-55115 after 1st line CT (advanced and relapse) cabozantinib vs. Placebo (cross over at relapse)
  - 6/54 pts included
- SCST
  - Alienor trial (GINECO) relapse after at least one line CT wPacl + bev vs wPacl alone (cross over to bev at relapse)
  - 43/60 pts already included

- All are randomized !
- All well recruited

3. Ovarian Clear Cell Trial Proposals- Stage IC2/3 & II

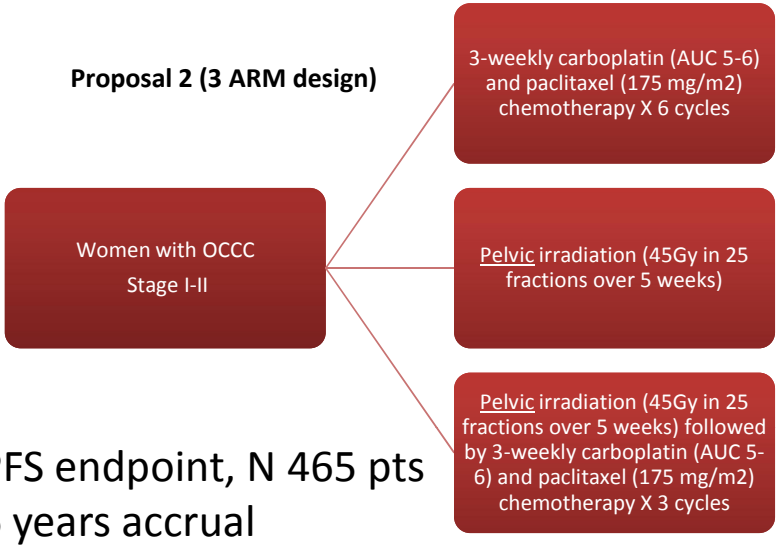
NCRI and NCIC

Proposal 1 (2 ARM design)



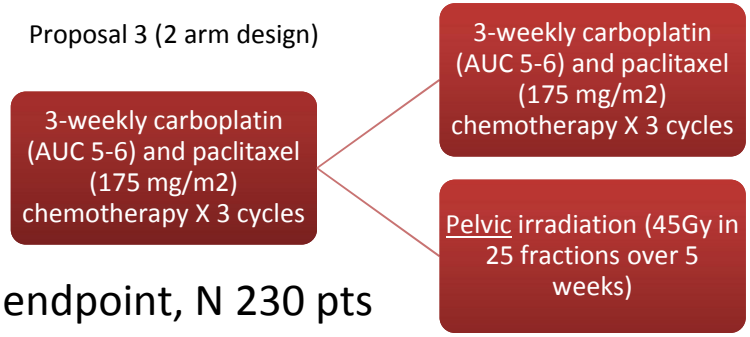
PFS endpoint, N 310 pts
6 years accrual

Proposal 2 (3 ARM design)



PFS endpoint, N 465 pts
6 years accrual

Proposal 3 (2 arm design)



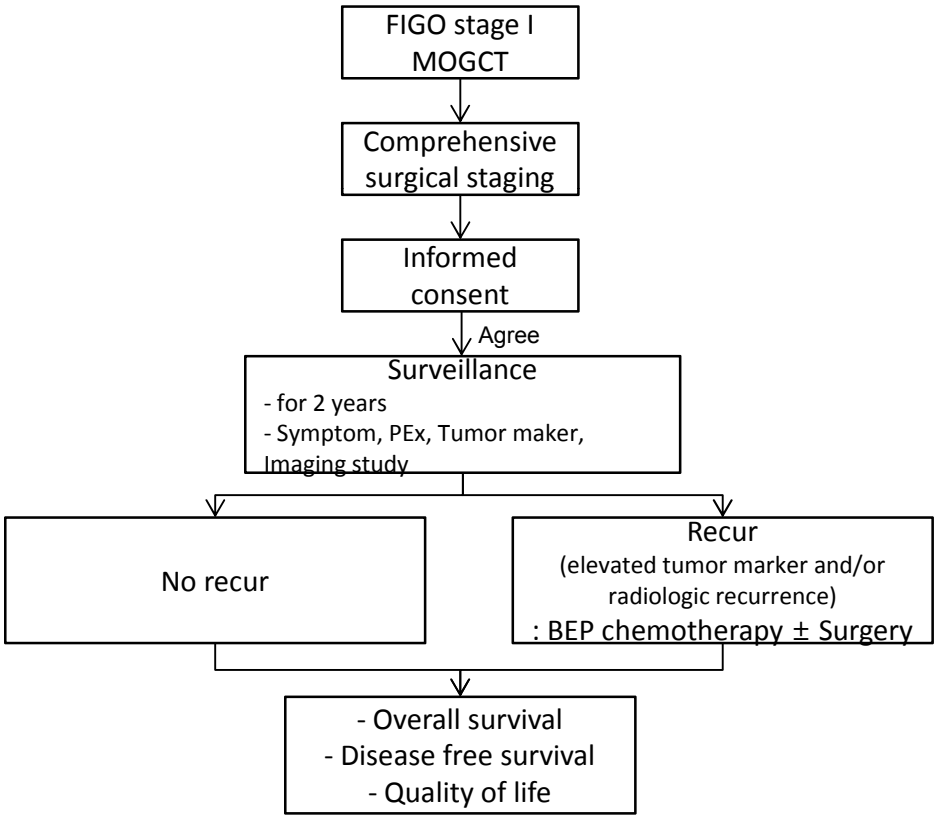
PFS endpoint, N 230 pts
3 years accrual

Recommendations & “To do List”

- Randomization definitively only for IC2/3 & stage II
- Redefine stat plan according to the 5th OCCC discussion
- Include endpoints dedicated to PROs
- Collect data (and tissue) on Stage 1A and other patients even if they are not entered into the randomization protocol
- Explore with the JGOG trial the sites of relapse in early stage disease
- Circulate a GICG survey to all national groups looking at interest & favorite model

4. Stage I MOGCT & surveillance

- KGOG 3033 study



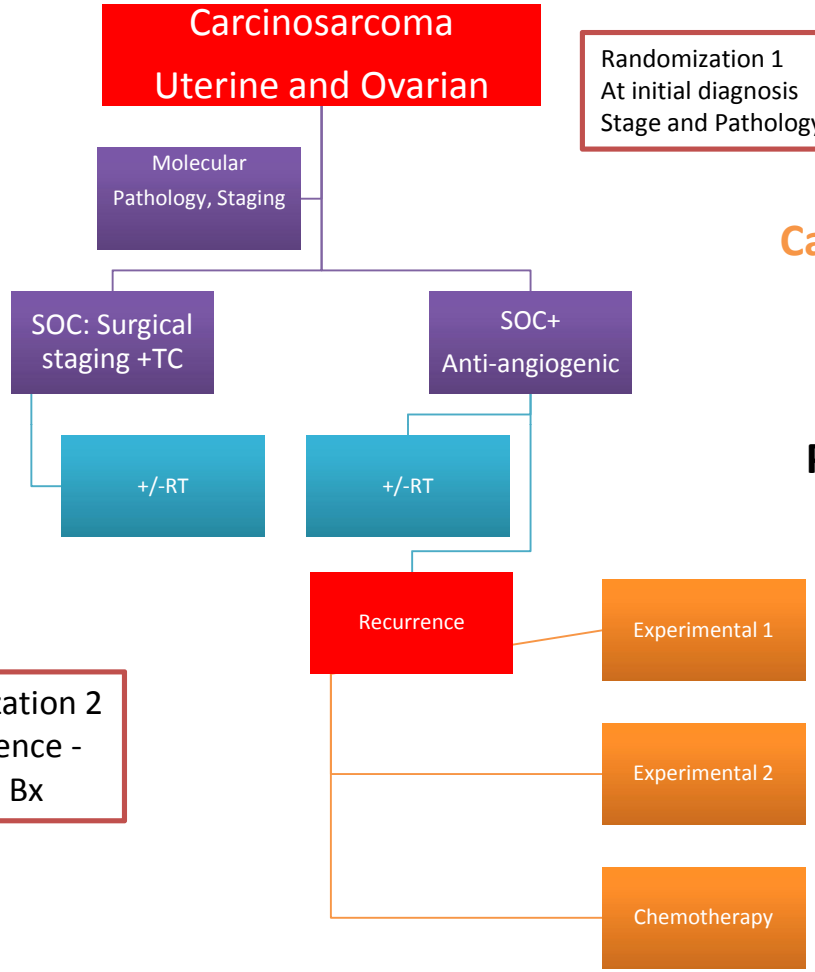
- Inclusion criteria
  - FIGO stage I
  - MOGCT all histologic types
  - Complete staging
  - Age: 0-70 years
- Endpoint
  - 3 years OS
  - 3 year PFS
  - Ovarian function
  - Treatment related complication
- Study duration 4 years
- N = 100 pts

Recommendations & “To do List”

- Revision of the protocol
  - the extent of surgical staging
  - Schedule of visit/markers/CT-scan for surveillance
  - Statistical plan needed if assumptions about expected 3 or 5 year survival, or recurrence free survival are set
  - Data registry will allow data on long term follow up to be collected
  - Include dedicated endpoints to PROs
- Get consent for patients not wishing to go on surveillance so that outcome data (especially tox) can be collected
- Next version before Chicago & proposal to national groups to participate

5. Ov & UT carcinosarcoma (PMHC project)

Patients can enroll At Randomization 1 or 2



Randomization 1
At initial diagnosis
Stage and Pathology

n= 100s

Carboplatin/paclitaxel plus Cediranib

Possibility to add/remove experimental arms

AKT inhibitor

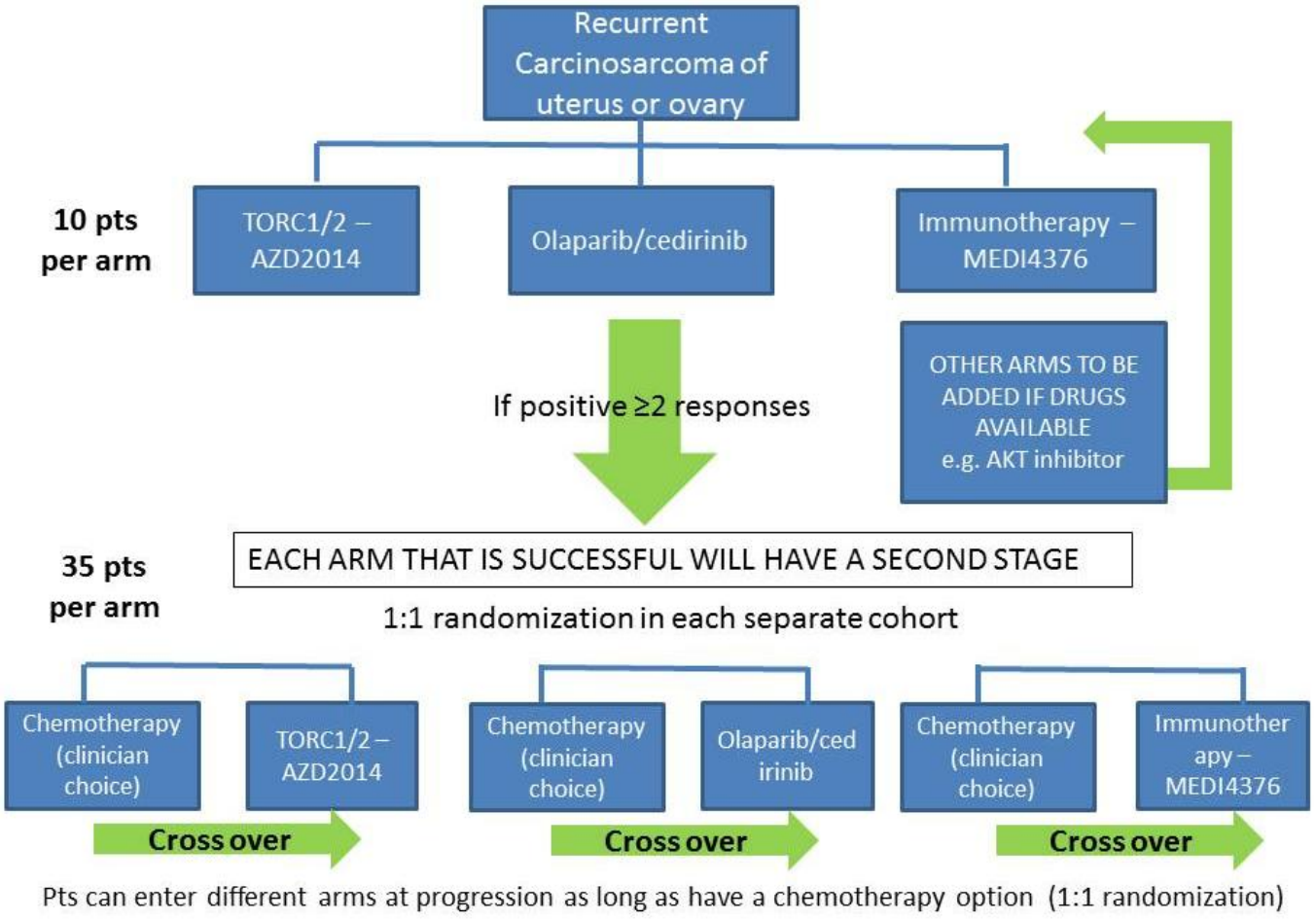
PARP inhibitor

Clinician choice?

Randomization 2
At Recurrence - Stage and Bx

N=100s

A randomized phase II trial MUlti-arm Study comparing targeted therapy with chemotherapy at recurrence in Carcinosarcoma of the ovary and uterus (MUSiC).



Recommendations & “To do List”

- Suggestion of combining ovary and uterus CS is an issue
  - Probably focus on Uterus
  - Endpoint of first section treatment considered optimistic. Increase in PFS from 8 to 13 months. Suggested that stats be reconsidered.
  - Defined guidelines for histologic diagnosis
- Recurrent study in 2 parts – run in 10 patients then randomization to a series of novel agents- umbrella design.
  - RR primary endpoint of both run in and randomization study - suggested that SD, or Prog-free at 3 or 6 months might be preferable.
  - First stage of recurrent disease probably more easily done by 1 group, the 2nd phase of the recurrent disease trials could be distributed although numbers per treatment group are small- 35.
- Include endpoints dedicated to PROs
- Next version is waited

6. GCIG SCCOHT Project

- **Summary 2014/2015:**
  - **Steering Committee: Clinicians, pathologist, scientist, study coordinator (operations), statistician**
  - **International Registry (prospective & retrospective)**
  - **Biorepository for TR**
  - **Registration of outcome data for efficacy on all CT regimens used (1st line therapy & relapse)**
    - **Helping us to upgrade the quality of GCIG guidelines**
    - **Potential trials of novel agents for relapsed patients**

Case Report Form - Small Cell Cancers of the Ovary (SCCO)

☐☐☐☐☐ Patient ID ☐☐☐☐☐ Center Initials ☐☐☐☐☐ Record number

1. PATIENT : DEMOGRAPHIC DETAILS

1.1 Date of Birth: ☐☐/☐☐/☐☐☐☐

1.2 investigator/group : _____

1.3 Pregnancy following medical management of cancer: ☐ Yes ☐ No ☐ Unknown

2. DIAGNOSIS

2.1 Date of diagnosis : ☐☐/☐☐/☐☐☐☐

2.2 First histological diagnosis : _____

2.3 Histological review in an expert Center : ☐ Yes ☐ No

2.3.1 *In case of histological review*, report reviewed diagnosis ☐ SCCOHT ☐ SCCOPT

Other (please specify): _____

2.4 Disease Stage *(The following stages are established according to the new FIGO classification, in effect since the 1st of January 2014, except in case of diagnosis established prior to this date. In this last case, the staging system used is the FIGO classification of 1988)*

☐ I ☐ II ☐ III ☐ IV ☐ Unknown

☐ A ☐ B ☐ C ☐ NA ☐ Unknown

If stage IV, localization of metastases _____

2.5 Tumor markers measurement *(prior to surgery)* :

2.5.1 CA125 : ☐☐☐,☐☐ unit ☐ ND

2.5.2 Hypercalcemia : ☐☐☐,☐☐ unit ☐ ND

2.6 Availability of Biological samples :

2.6.1 Tumor sample available: ☐ Yes ☐ No

2.6.2 Blood sample available: ☐ Yes ☐ No

Case Report Form - Small Cell Cancers of the Ovary (SCCO)

☐☐☐☐☐ Patient ID ☐☐☐☐☐ Center Initials ☐☐☐☐☐ Record number

3. FIRST-LINE THERAPY

3.1 Chemotherapy : ☐ Yes ☐ No ☐ Unknown

3.1.1 If yes: ☐ Neo adjuvant ☐ Adjuvant ☐ Both

3.1.2 Chemotherapy regimen : ☐ Carboplatin + Etoposide ☐ Cisplatin + Etoposide

Other (please specify) : _____

3.1.3 Number of cycles : ☐☐

3.1.4 High dose chemotherapy : ☐ Yes ☐ No

3.1.5 Treatment end date : ☐☐/☐☐/☐☐☐☐

3.2 Primary Surgery : ☐ Yes ☐ No ☐ Unknown Date : ☐☐/☐☐/☐☐☐☐

3.2.1 Fertility-sparing surgery : ☐ Yes ☐ No ☐ Unknown

3.2.2 Type of surgical resection :

☐ Tumorectomy/Kystectomy ☐ Ovariectomy ☐ Unilateral Salpingo-oophorectomy

☐ Bilateral Salpingo-oophorectomy ☐ Partial hysterectomy ☐ Total hysterectomy

☐ Omentectomy ☐ Peritoneal cytology ☐ Lymphadenectomy

Other (please specify) : _____

3.2.3 Tumor rupture : ☐ Yes ☐ No ☐ NA

3.2.4 Quality of surgical resection : ☐ CC0 ☐ CC1 ☐ CC2 ☐ NA

3.3 Revision surgery : ☐ Yes ☐ No ☐ Unknown Date : ☐☐/☐☐/☐☐☐☐

3.3.1 Type of surgical resection :

☐ Ovariectomy ☐ Unilateral Salpingo-oophorectomy ☐ Bilateral Salpingo-oophorectomy

☐ Partial hysterectomy ☐ Total hysterectomy ☐ Omentectomy

☐ Peritoneal cytology ☐ Lymphadenectomy

Other (please specify) : _____

3.3.2 Quality of revision surgery : ☐ CC0 ☐ CC1 ☐ CC2 ☐ NA

3.3.3 *In case of multiple revision surgeries*, date of last revision surgery: ☐☐/☐☐/☐☐☐☐

3.4 Adjuvant radiotherapy: ☐ Yes ☐ No ☐ Unknown

3.5 End treatment response : ☐ CR ☐ PR ☐ SD ☐ PD ☐ NA

Recommendations & “To do List”

- Data form to be circulated.
- Enquiries re cost of accessing :
  - Redcap or Cartwheel database (Clare Scott).
  - Mario Negri database (Heavy base?) Free of charge? (Nicoletta Colombo to investigate).
  - Mega database group (Ros Glasspool)
- Many countries have emerging RT registries. The step from registry to clinical data collection needs to be made by most.
- GCIG survey (Ray-Coquard) will circulated to national group :
  - National organization yes/no
  - National barrier to send data
  - Estimated nb of patients
  - On going collection of tumors
- 1st initiative to collect retrospective information from national groups via Excel files to have quick information available