

GCIG RARE TUMOR Working Group

Thursday 30th June 14:00 a.m. – 16:00 am


Chicago

MINUTES

I.Ray-Coquard (Chair), J.Ledermann (co-Chair)

Attendees:

WELCOME, INTRODUCTIONS, CONFLICTS OF INTEREST DISCLOSURES



RARE TUMOURS Working Group
Thursday, May 28, 2015, 2:00pm – 4:00pm
State I Room, DoubleTree Hotel, Chicago

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: November 2014 5 min

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: 10 min

- Update on BIBF1120: Ros Glaspool
- Update on PARAGON Trial: Michael Friedlander
- Update on Allenor trial: I Ray-Coquard

3. New proposals: 50 min

- New project on first line CCC Ov
- 2nd project dedicated to CCC Ov
- New project for germ cell tumors
- NRG proposal for SCC tumors
- Registry for SCC, next steps

4. Future Directions: all 35 min

1 GCIG Rare Tumor report:

GCIG recommendations & RTWG meeting London Nov. 2013

• Publications :



- One paper summarizing all documents (non answered questions)
- one paper to summarize London meeting (500 words per section) harmonization, statistical, biology and specific recommendations for very very rare, rare and not so rare disease



- Proposal from ESGO : a chapter dedicated to GCIG guidelines for rare tumors in the textbook ! → I would like to say yes for you
 - × Authors: 20 coordinators + Chair of GCIG in 2013



• Smartphone application dedicated to GCIG reviews

- Proposal from 360 medical, financial support need to be determined
- 1st Alternative to develop our own Mobile phone apps
- 2nd : to negotiate an open access with IJGC
- In charge, Jonathan Lederman

IndependentApps

- « 360 medical » apps?
- UX is the success Key Factor for apps
- Dynamic tables of contents: accurate information
- Technology 360 medical: fast loading



Agreement from Ex-Co is waiting for smartphone application project and financial support

2. Clinical trial on - going:

NiCCC Nintedanib in Clear Cell Carcinoma

A Randomised Phase II Study of BIBF 1120 versus
Chemotherapy in Recurrent Clear Cell Carcinoma of the
Ovary or Endometrium

SGCTG/NCRI/NSGO



NiCCC Trial Design



Now open for inclusions!



Paragon

A Phase II study of aromatase inhibitors in women with potentially hormone responsive recurrent/metastatic gynaecological neoplasms



Tumour Subgroup Accrual

Tumour Subgroup	Accrual
*Ovarian - Asymptomatic patients with rising CA125 markers	54
Ovarian - Low Grade / Borderline Tumours	23
*Ovarian - Platinum Resistant / Refractory	53
*Endometrial Carcinoma	83
Endometrial Stromal Sarcomas	14
Miscellaneous Sarcomas	27
Granulosa Cell & Sex Cord Stromal Tumours	32

**Tumour subgroups have met accrual target and are now closed to recruitment*



Trial Status

Country/Group	Sites	Accrual
ANZGOG	23	205
United Kingdom	23	80
Belgium	1	1
TOTAL	47	*286

*Accrual target is 350 patients



Transparagon trial is on going to be organized



ALIENOR

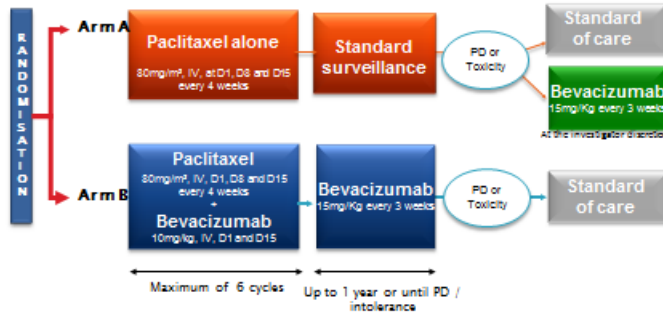
ENGOT-OV7

Avastin and weekly paclitaxel use in sex-cord-stromal ovarian tumors

A randomized, open label, phase II trial of bevacizumab plus weekly paclitaxel followed by maintenance with bevacizumab monotherapy versus weekly paclitaxel followed by observation in patients with relapsed ovarian sex-cord stromal tumors



ALIENOR DESIGN : 60 patients

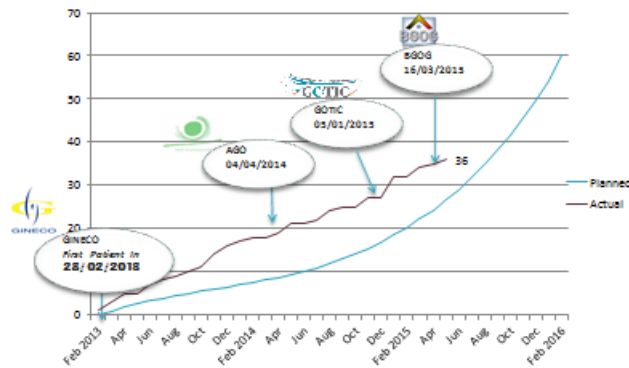


Population :
Patients with an histologically confirmed diagnosis of ovarian sex-cord stromal tumor in relapse after a platinum-based chemotherapy.

Primary objective :
Clinical benefit rate (non-progression rate after 6 months of treatment)

Stratification
Anterior chemotherapy lines : 1 or 2 vs 3 and more
Platinum Free Interval (PFI) <12 months vs ≥12 months

ALIENOR Status



Submission in June

- Enrollment period : 36 months
 - Treatment + maintenance : 18 months
 - Follow-up : 36 months
- First Patient In : February 2013
Last Patient Out of Maintenance : August 2017
Last Patient Out : August 2020

First interim analysis

Assessment of clinical benefit at 6 months of the first 20 patients

»ALIENOR Independent Data Monitoring Committee IDMC ([A Zeimet](#), A Poveda, F Bonnetain) met on 09/02/2015 and reviewed unblinded safety and efficacy data of the 20 first patients.

- » There was full agreement that so far the study does not bear major safety concerns.
- » the study is well conducted, that there were no unusual protocol violations and deviations.
- » The committee voted unanimously that ALIENOR should continue unchanged.

»Next step will be the 2nd interim analysis (n = 40)



3. New projects

3.1. Clear cell carcinoma (ovarian localization)

Background for adjuvant TTT in OCCC

- OCCC rare & distinct subtype of EOC 5-25% of all cases
- 47-80% stage I/II at diagnosis of other EOC
- Most OCCC studies are retrospective /single institution and from Japan
- Lack of consensus on adjuvant treatment
- Relapsed disease refractory to chemo
- Some reports suggesting RT reduces relapse

Early stage CCC ovarian carcinoma

- **2 proposals:**
 - From NRCN (Mary McCormack)
 - × Stage IC to II
 - × Pelvic radiotherapy vs 6 cycles CP
 - × Phase III trial,
 - × PFS HR 0,65; n≈ 500/600pts
 - From Canadian group (reported by Iain McNeish)
 - × Stage IC2 to II
 - × 3 cycles CP then @ 3 cycles CP vs pelvicRT
 - × Randomized phase II
 - × N= 106 pts, OSHR 0,6

Early stage CCC ovarian carcinoma

- **Recommandations:**
 - Only one Clinical trial
 - No stage IA or IB (excellent prognosis)
 - Central review of the histology
 - Optimal control arm not clearly defined
 - × JGOG currently evaluated obs vs CT
 - Late toxicity major issue for RT
 - Surgery need to be clearly defined

➤ All questions will be circulated

➤ Final version for Nov 2015

3.1. GCT proposals

Proposed International Malignant GCT Trial

- **From the MAGIC consortium (A. Lindsay Frazier):**
- **GCT (testis & ovarian) child & adult**
 - Low risk (FIGO Stage IA/B): observation only after surgery
 - Intermediate Risk (FIGO Stage II, III): RCT of JEB vs. BEP
 - Poor Risk (FIGO Stage IV): RCT of BEP vs. T-BEP vs. Accelerated BEP or TIP.
- **Need for a GCIG participation, however, not a GCIG trial until today**

4. Small Cell Carcinoma registry project

Previously on 2014:

SCCOHT

- **Rare and highly aggressive**
- **Most patients die within 2 yr. of diagnosis**
- **Mean age = 24 yr.**
- **Usually unilateral (option for FSS)**
- **More frequently advanced stage**
- **Germline and somatic SMARCA4 mutations characterize this tumor**
- **SCCOHT = malignant rhabdoid tumor**

GCIG SCCOHT Project

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

So, today next steps will be:

SCCOHT, next steps

- **1st registry including retrospective & prospective data on treatments & survival + availability of tumors +/- blood:**
 - Coordinator & Steering committee will be defined
 - × Call for application (now)
 - Objectives: description of the clinical management & prognosis, identification of patients & tumor samples
 - To be included in the mega databasis project?
- **2nd point: clinical trial dedicated to SCCOHT**
 - Drugs : BRM-ATPase inhibitors , HDAC inh,
 - Major Questions & Design

Adjourn