Trial setting: **Sex chord-stromal ovarian tumors**

Study Design: **Randomized, open label, phase II trial**

Intervention: **Bevacizumab VEGF-A inhibitor**

Sponsor(s): **ARCAGY-GINECO**

Final No. of patients: **60**

Timeline (first patient – trial closing): **Feb 2013- Aug 2021**

Publications:

Planned publications: **Q3 2017**

Planned substudies:
A multi-centre, randomized, open label, phase II trial of Bevacizumab plus weekly Paclitaxel then Bevacizumab monotherapy in maintenance versus observation in patients with relapsed ovarian sex-cord stromal tumours

- Primary analysis (Q2-Q3 2017)
- for primary endpoint (ASCO 2018)
- 2nd endpoints PFS, PFS2, cross-over, OS
- Translational 50/60 tumor blocks
- Substudies ....
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

Intervention: Cabozantinib **C-MET and VEGFR2 inhibitor**

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),
- Amendment to open the inclusion to all high grade uterine sarcoma, including LMS, adenosarcoma and HG ESS – warranted as subgpcs not that discrete
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.
## Trial setting: tumour type/stage
Progressive or recurrent ovarian and endometrial CCC within 6 months of previous platinum

## Study Design:
Open Label Randomised Phase II Study

## Intervention:
Nintedanib/BIBF **PDGFR, FGFR, VEGFR2 inhibitor**

## Sponsor:
NHS Greater Glasgow & Clyde

## Planned No. of patients:
90 Ovarian and up to 30 endometrial

## Current accrual:
32

## Other important information:
Open Sites: UK: 16, France: 16

## Additional Participating Countries:
The Netherlands, Denmark, Spain, Portugal, Italy, Belgium still to open
A randomised phase II study of Nintedanib (BIBF1120) compared to chemotherapy in patients with recurrent Clear Cell Carcinoma of the ovary or endometrium.

**Control Arm: Chemotherapy**
- Ovary:
  - PLD (40mg/m² day 1q28)
  - Weekly Paclitaxel (80mg/m² day 1, 8, 15 q28)
  - Weekly Topotecan IV (4mg/m² day 1, 8, 15 q28)

- Endometrium:
  - Carboplatin (AUC 5) /Paclitaxel 175 mg/m² q21
  - Doxorubicin 60mg/m² q21

**Experimental Arm: Nintedanib**
Nintedanib 200mg bd until progression.
**NRG Oncology**

**DAVID GERSHENSON**

**Trial setting: tumour type/stage**
Stage II-IV, primary low-grade serous carcinoma of the ovary or peritoneum

**Study Design:**
Randomized, 3-arm phase III trial

**Intervention:**
Letrozole Aromatase Inhibitor vs chemo

**Sponsor:**
NRG

**Planned No. of patients:**
350 pts (250 to chemo; 100 to letrozole)

**Primary endpoint:**
PFS

Design still under review - ? One or two randomisations, ? extension
A randomized, 3-arm phase III trial of paclitaxel/carboplatin versus paclitaxel/carboplatin/maintenance letrozole versus letrozole monotherapy in patients with stage II-IV, primary low-grade serous carcinoma of the ovary or peritoneum

Letrozole drug supply
Letrozole
Is CT→Obs arm acceptable? yes
Is letrozole only acceptable? no
Duration of Letrozole? no placebo involvement as all standard of care
Use of bevacizumab? placebo not feasible
? willing to enroll without HMT
Ditto reverse
Until PD at the moment; except they are often young
Not used in US; is used in Europe
Feasibility of parallel trials
with single data center
TR biomarkers
Trial setting: tumour type/stage

Radiotherapy in Ovarian Clear Cell Cancer

Study Design: Randomized, 2-arm phase II trial

Intervention: Chemo +/- Radiotherapy

Sponsor: CRUK UCL

Planned No. of patients: 350 pts

Primary endpoint: Median DFS at 5 years

Translation and funding pending
Gestational Trophoblastic Disease

GOG-0275: A PHASE III RANDOMIZED TRIAL OF PULSE ACTINOMYCIN-D VERSUS MULTI-DAY METHOTREXATE FOR THE TREATMENT OF LOW-RISK GESTATIONAL TROPHOBLASTIC NEOPLASIA
Study Chair: Julian Schink, MD

Phase II trial of anti-endoglin antibody (TRC105) without or with bevacizumab in relapsed high risk GTN
4 patients recruited: 1 CR and 2 PD and 1 starting
ENGOT/ESGO PLANS FOR RARE CANCERS

• A plan to improve research for rare gyn cancer in ENGOT
• Close collaboration and regular update to GCIG

45 different projects (retrospective, prospective registries phase 2 trials)
  23 projects happy for external collaboration
  10 projects overlapping, possibly able to merge
  2 projects combine registry and tumour sample collections
→ Meeting in September 2017
→ to present the projects and to discuss collaboration or improvement ....

GCIG IS THE UMBRELLA OVER ALL THE INDIVIDUAL GROUP PLANS TO STREAMLINE RARE TUMOUR MANAGEMENT AND RESEARCH
NEW RARE TUMOUR DATABASE

CLARE SCOTT

- REDCap Platform (academic, only need one license per country)
- Generic for all rare tumours; common consent form (prototype)
- Built by BioGrid Australia (NFP) for COSA rare cancer group and WEHI
- Funded by philanthropy: Stafford Fox Medical Research Foundation
- Available for free to any groups, updates supported for 5 years
- Beta testing in next 2-3 months – contact: kee.d@wehi.EDU.AU
- Data could be uploaded into a central portal, NCI Genomic Data Commons: Treat Rare Collect data and Share – TRICEPS
  Once data has been published by primary source