



Gynecologic Cancer Intergroup (GCI)

**ENDOMETRIAL CANCER COMMITTEE
8:00am – 11:30 am, May 31, 2013
LaSalle I Room, Doubletree Hotel, Chicago**

AGENDA

*****Please sign-in on Attendance Forms*****

Chair: Ketta Lorusso Co-Chair: Stefano Greggi

Please sign-in on Attendance Forms

Disclosures: (real or perceived) Conflicts of Interest

Welcome and Introductions

Lorusso

Guests Remarks:

RTwg Chair
ISSTD rep. (GTD)
Thai guest (GTD)
Others

Ray-Coquard
Seckl/Schink
Boonlert

**ENDOMETRIAL CANCER CLINICAL TRIALS PLANNING MEETING -
FOLLOWUP**

1) Translational Research initiative

McNeish

Phase II working group

Oza

2) Conservative Treatment

- Conservative treatment of endometrial cancer; a multicentre registry study Greggi

- feMME Trial: Mirena & Metformin in Endometrial Cancer Quinn for Obermair

3) Surgery

- lymphadenectomy trial concept

Kitchener & Creutzberg

4) Carcinosarcoma

A phase II study to investigate the feasibility, efficacy and toxicity of a combined regimen of radiotherapy and chemotherapy for patients with carcinosarcoma of the endometrium

Quinn

5) Symptom Benefit

Joly & McAlpine

BREAK --- continental breakfast.

GCIG STUDIES FOR BRIEF UPDATES & REVIEW:

Endometrial Staging

- **KGOG 2015:** Multi-center Prospective Observational Study for the Validation of Preoperative Low-risk Criteria for Lymph Node Metastasis in Endometrial Cancer ([NCT01527396](#)): Kang/Kim

Endometrial Adjuvant

- **DGCG:** A Phase III Trial of Postoperative Chemotherapy or no Further Treatment for Patients With Node-negative Stage I-II Intermediate or High Risk Endometrial Cancer ([NCT01244789](#)): **NSGO, AGO, BGOG, EORTC, MANGO, MITO** Mirza
- **DGOG PORTEC-3:** Randomized Phase III Trial Comparing Concurrent Chemoradiation and Adjuvant Chemotherapy with Pelvic Radiation Alone in High Risk and Advanced Stage Endometrial Carcinoma ([NCT00411138](#)) – **MaNGO, ANZGOG, NCRI, and NCIC-CTG. NSGO interested.** Creutzberg
- **DGOG PORTEC4:** Randomized trial of vaginal brachytherapy vs observation for high-intermediate risk endometrial carcinoma Creutzberg
- **GOG-0249:** A Phase III Trial of Pelvic Radiation Therapy versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Cancer ([NCT00807768](#)) – **RTOG** Miller
- **GOG-0258:** A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial ([NCT00942357](#)) – **RTOG** Miller

Endometrial Follow Up

- **MaNGO TOTEM Trial:** Appropriateness Evaluation of Follow up Procedures in Gynaecology Oncology **TOTEM** Study: Multicentric Randomized Controlled Clinical Trial Between Two Follow up Regimens With Different Tests Intensity in Endometrial Cancer Treated Patients (NCT00916708) Katsaros for Zola

Endometrial Advanced/Recurrent:

- **GOG-0238:** A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-only Recurrence of Carcinoma of the Uterine Corpus (NCT00492778) – **RTOG** . Miller
- **MITO BEVA END:** Randomized phase II trial on Carboplatin-Paclitaxel vs Carboplatin-Paclitaxel Bevacizumab in patients with advanced (stage III-IV) or recurrent endometrial cancer. Lorusso
- **NSGO:** A randomized phase II trial of first line combination chemotherapy with BIBF1120/placebo for patients with advanced or recurrent endometrial cancer. Mirza

RARE TUMORS -- ENDOMETRIAL CANCER:

- **Endometrial Clear Cell EN 2:** Randomised Phase II Study of BIBF 1120 compared to Chemotherapy in Patients with Recurrent Clear Cell Carcinoma of the Ovary or Endometrium" **SGCTG, NSGO, EORTC, GINECO** Glasspool
- **Uterine Leiomyosarcoma GOG0277 (UC1009):** A Phase III Randomized Trial of Gemcitabine (NSC# 613327) Plus Docetaxel (NSC# 628503) Followed by Doxorubicin (NSC# 123127) v. Observation for Uterus-Limited, High Grade Uterine Leiomyosarcoma (NCT01533207). Miller for Hensley
- **Uterine Carcinosarcoma GOG-0261:** A Randomized Phase III trial of Carboplatin plus Paclitaxel VERSUS Ifosfamide plus Paclitaxel in Chemotherapy Naïve Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus (NCT00954174) – **Interested: NCRI, GINECO, JGOG, RTOG** Miller

Trophoblastic neoplasia:

- **GOG-0242:** A Phase II Study to Determine the Response to Second Curettage as Initial Management for Persistent Low Risk, Non-Metastatic Gestational Trophoblastic Neoplasia (NCT00521118) Schink
- **GOG0275 (UC1005):** A Phase III Randomized Trial of Pulse Actinomycin-D Versus Multi-Day Methotrexate for the Treatment of Low-Risk Gestational Trophoblastic Neoplasia (NCT01535053): Schink
- **GOG/ISSTD:** A randomized phase ii trial comparing the toxicity of paclitaxel etoposide (TE) alternating two weekly with paclitaxel and cisplatin (TP) with etoposide and cisplatin (EP)

alternating weekly with etoposide, methotrexate and dactinomycin (EMA) in GTN patients failing non platinum based combination agent therapies. Seckl

ACTION ITEMS:

- 1) by the end of September 2013, in order to activate the trials among interested groups before the next GCIG Endometrial Cancer Committee meeting:
 - a) finalize and circulate the lymphadenectomy trial protocol;
 - b) finalize and circulate the conservative treatment trials protocols;
 - c) finalize and circulate and the carcinosarcoma trial protocol.
- 2) To continue collaboration with the GCIG Rare Tumours working group in development of GCIG Guidelines for management and research of Rare Tumours. And, to foster closer partnerships with other societies (ie: ISSTD, WSN) in order to continue development of common guidelines for the treatment of rare uterine cancers (leiomyosarcoma, GTD) and facilitate collaborative design and conduct of trials.
- 3) To increase the impact of translational research; thus encouraging the possibility to include a sub study with a translational end-point in any present and future endometrial cancer clinical trial.
- 4) To identify better instruments to evaluate quality of life of endometrial cancer patients and examine/utilize those within clinical trials.

ADJOURN

The next GCIG Endometrial Cancer Committee meeting will be held in London, November 2013