**Proposal for Discussion**

# Randomised Trial of Cediranib and Olaparib Maintenance in Patients with Relapsed Platinum Sensitive Ovarian Cancer

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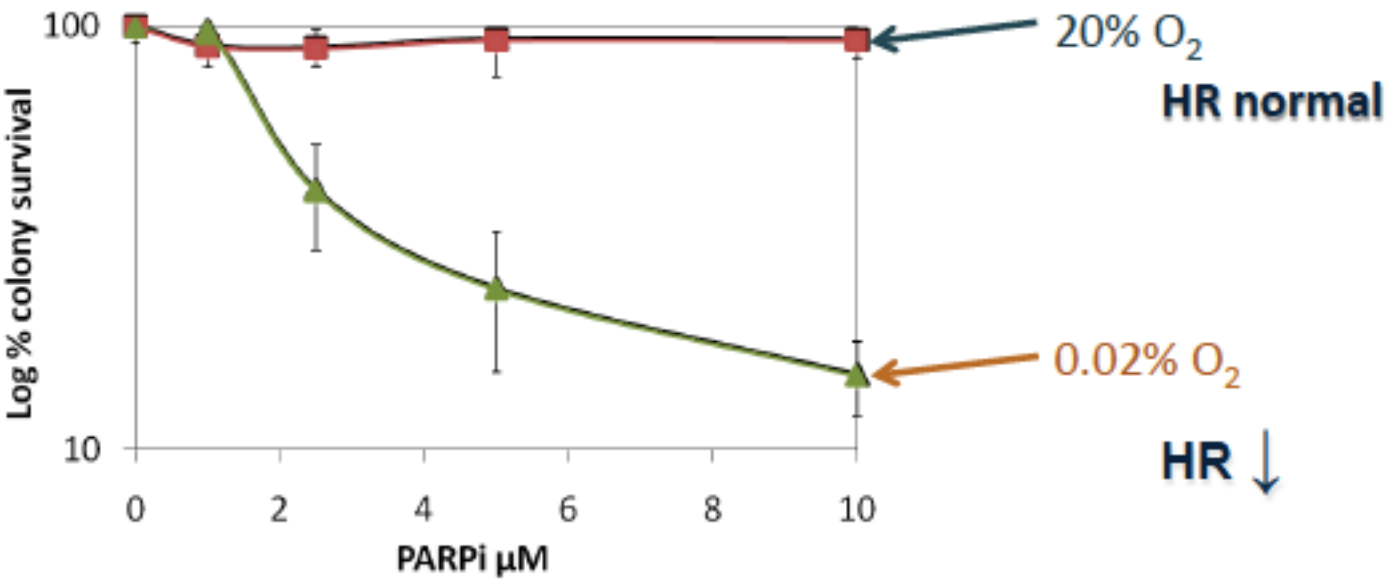
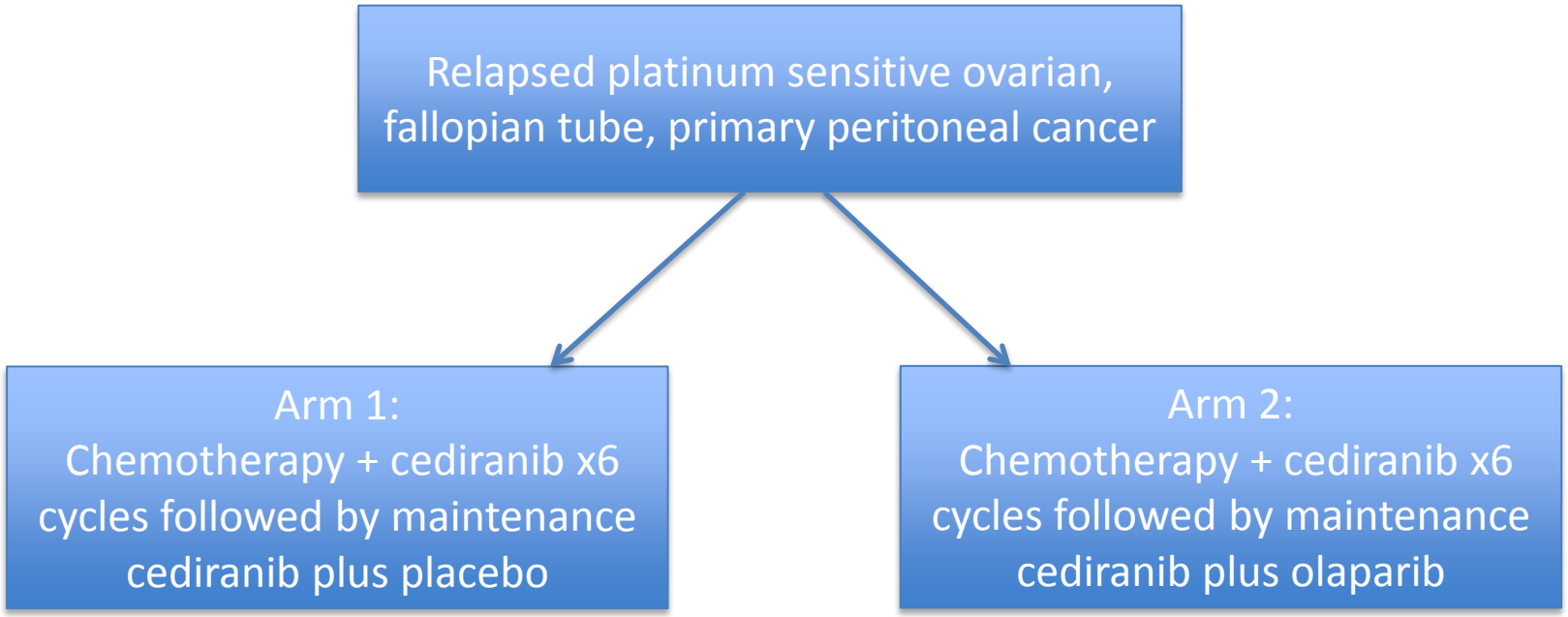
# Hypoxic cells are sensitive to PARP inhibition *




*E Hammond and A Harris

# Randomised trial of cediranib and olaparib maintenance in patients with relapsed platinum sensitive ovarian cancer




Patients will be randomised with stratification for BRCA status, time from previous platinum therapy (6-12 months; >12 months).
Chemotherapy: platinum-based combination ( as per ICON6 )
Cediranib: 20 mg OD
Olaparib: 300 mg BD

# Main Inclusion Criteria

- epithelial ovarian carcinoma, fallopian tube carcinoma or primary serous peritoneal carcinoma requiring treatment with further platinum-based chemotherapy more than 6 months after their last cycle of first-line chemotherapy
- Minimum of 6 weeks after maintenance that is not chemotherapy based ( if given).
- CT or MRI proven relapsed disease (measurable or non-measurable).
- ECOG performance status 0-1
- Able to swallow and retain oral medications.
- Adequate haematological and renal function

# Main Exclusion Criteria

- Non-epithelial ovarian cancer, including malignant mixed Mullerian tumours and mucinous carcinoma of the peritoneum
- Poorly controlled hypertension (persistently elevated > 150/100mmHg, either systolic or diastolic or both, despite anti-hypertensive medication)
- History of inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)
- History of cerebrovascular accident (including transient ischemic attacks) within last 12 months.
- GI impairment that could affect ability to take, or adsorption of, oral medicines including sub acute or complete bowel obstruction

# Study Objectives/Endpoints

To assess the efficacy of **maintenance cediranib in combination with olaparib**

| | End points |
|---|---|
| **Primary Objective** | Progression free survival (RECIST v1.1) (PFS) |
| | |
| **Secondary objectives** | OS<br>Progression free survival by CA125 - GCIG criteria |
| To assess the safety and tolerability of cediranib in combination with olaparib | Adverse events using CTCAE v4.0<br>Quality of Life |
| **Exploratory objectives** | **End points** |
| Activity of subsequent platinum based chemotherapy | PFS2* |