ICON 9

An international phase III randomised study to evaluate the efficacy of maintenance cediranib and olaparib combination therapy in patients with relapsed platinum-sensitive ovarian cancer following platinum-based chemotherapy

NCRI National Cancer Research Institute

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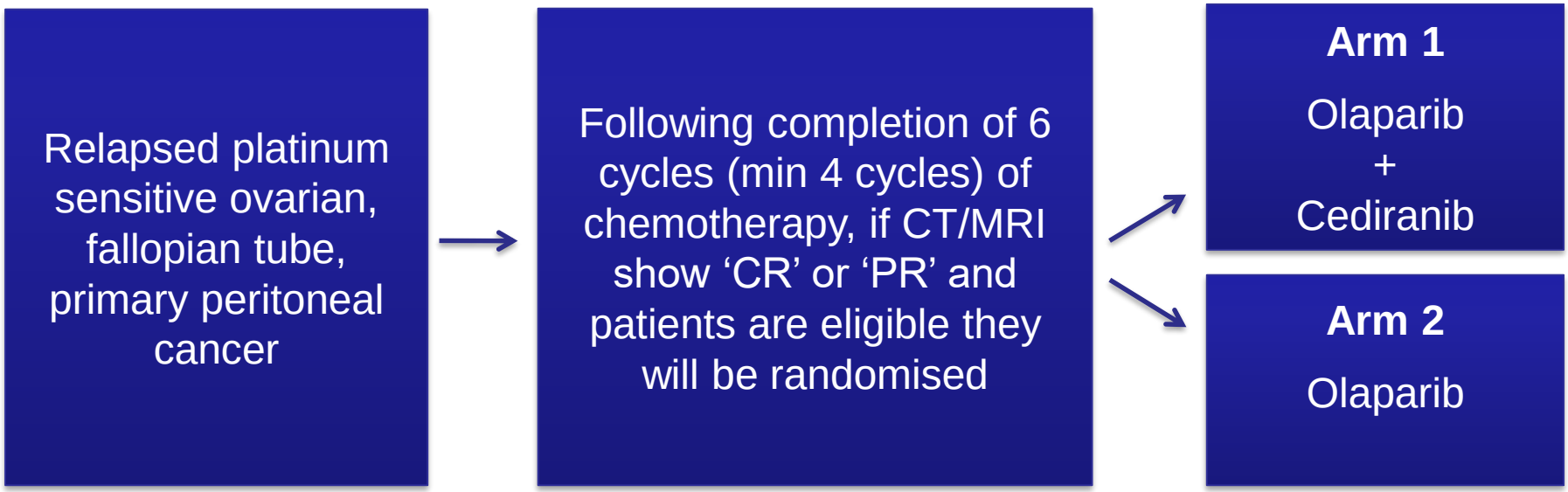
GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

Trial Schema



Stratified by 6-12 vs >12 month progression free interval; surgery vs no surgery at relapse prior to chemotherapy; prior bevacizumab therapy; BRCA status; HRD status

Olaparib: 300 mg BD
Cediranib: 20 mg OD

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Study Objectives

ICON 9 will assess the efficacy, safety and tolerability of maintenance olaparib in combination with cediranib compared to maintenance of olaparib alone in patients who have received combination platinum-based chemotherapy

Study Endpoints

	End points
Primary Objective	• PFS (RECIST v1.1) • OS
Secondary objectives	• Toxicity • Adherence • PFS2 • Time to subsequent treatment • Quality of Life (FACT-O/TOI) and Patient Reported Outcomes and EQ-5D-5L (health economic analysis) • Progression free survival by CA125 – GCIG criteria • Response rates by RECIST/CA125 at 12 weeks of maintenance therapy in patients with measureable disease or elevated CA125 at randomisation to maintenance therapy

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Details

- AZ remain supportive of trial
- 35 UK sites
- 45 international sites from 5 countries
- September 2015: Full CRUK application approved in UK
- Funding approved in Australia and Canada
- Q1 2017 (open trial)

- **GCIG Satellite meeting Friday 28th October at 9am in Augusta II Room**

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