

# OPEB-01 –APGOT OV4

## OPEB-01

A single-arm phase II study of **O**laparib maintenance with **P**embrolizumab & **B**evacizumab in BRCA non-mutated patients with platinum-sensitive recurrent ovarian cancer

Trial setting: ovarian cancer/platinum-sensitive

Study Design: a phase II study

Participating Groups: APGOT-Korea, GCGS

Sponsor: Yonsei University College of Medicine

Status: Ongoing (Screened : 8/Enrolled : 6/Ongoing : 6)

Grant support: Not determined

Drug supply: MSD

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Single arm phase II , Total n=44  
Primary endpoint : 6 months PFS rate

**Recurrent BRCA wild-type OC**

**Nonmucinous OC**  
**No Germline and tumor BRCA mutation**  
≥6 mon after 1<sup>st</sup> line CT  
ECOG 0 or 1

**Platinum-based chemo  
± Bevacizumab**

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**Olaparib + Pembrolizumab +  
Bevacizumab**

Simon's two-stage optimal design  
5% sig, 1-sided  $\alpha$ ; 80% power  
H0 6m PFS rate = 50% ; H1 6m PFS rate = 70%

- IRB(Approved on 02 Jun 2020 at Yonsei)
- IND(Approved on 02 Jun 2020 in Korea)
- Contract with MSD (MISP# 59516, Protocol#: 3475-B32)
- IP delay issue / Support up to 4 sites by MSD
- NCT04361370 , KCT0005144

	Group	IRB	IND
Yonsei	APGOT-K	Approved	Approved
NCC, SMC	APGOT-K	Under review of IRB	-
NUHS	GCGS	Under review of IRB	-