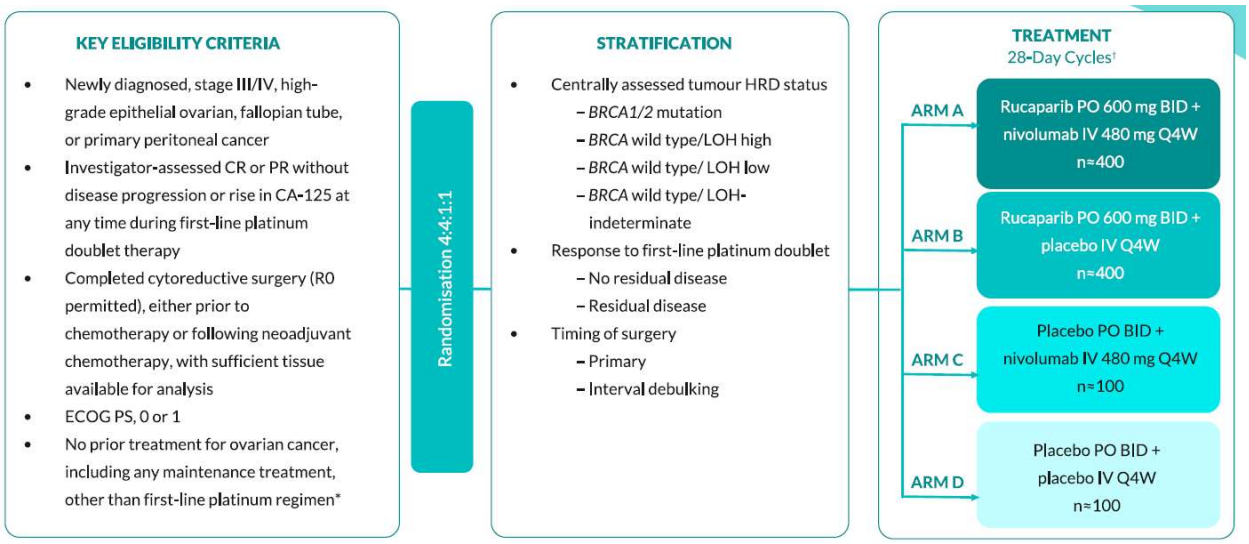
GOG-3020 / ENGOT-ov45 / ATHENA / AGO-OVAR 25

Study Title	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study in Ovarian Cancer Patients Evaluating ˇRucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy
Sponsor	Clovis Oncology, Inc.
Protocol	CO-338-087
Clinicaltrials.gov identifier	NCT03522246
Phase	III
Study Design	Randomized (4:4:1:1), double-blind, 4-arm, placebo-controlled, multicenter



*Bevacizumab is allowed during the chemotherapy phase, but not during maintenance, ie, during treatment in this study.

†First Dose of IV study drug will be administered on day 1 of cycle 2; study treatment will continue on day 1 of every 28-day cycle thereafter

Treatment and Assessments	• Safety follow-up 28 days and 5 months after last dose • Treatment for 24 months, or until radiographic progression, unacceptable toxicity, or other reason for discontinuation • Disease assessment per RECIST every 12 weeks • Safety and PRO assessment each cycle
Long-Term Follow-Up	• Tumor assessments every 12 weeks for 3 years and 24 weeks thereafter for patients who discontinue for a reason other than progression • All patients will be followed for survival, subsequent treatments, and secondary malignancies • Patients receiving clinical benefit may continue treatment beyond progression for up to 24 months
Study Endpoints	Response to treatment will be analyzed based on HR status of tumor samples <u>Primary Endpoint:</u> • PFS by Investigator in molecularly-defined HRD subgroups <u>Key Secondary Endpoints:</u> • PFS by BICR in molecularly-defined HRD subgroups • Investigator-assessed ORR and DOR in patients with measurable disease • OS and Safety

Neither rucaparib nor nivolumab have been demonstrated to be safe or effective, nor have they been approved by any regulatory authority, including the European Medicines Agency (EMA) and the US Food and Drug Adminstration (FDA), for use in combination for these disease indications.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

BICR=blinded independent central review; BID=twice daily; BRCA=breast cancer susceptibility gene; CA-125=cancer antigen 125; CNS=central nervous system; CR=complete response; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group Performance Status; FIGO=International Federation of Gynecology and Obstetrics; HR=homologous recombination; HRD=homologous recombination deficiency; IV=intravenous; LOH=loss of heterozygosity; Q4W=every 4 weeks; R0=total cytoreduction; RECIST=Response Evaluation Criteria in Solid Tumours version 1.1.

Reference: Monk B, et al. International Gynecologic Cancer Society (IGCS), September 2018, Kyoto, Japan, Abstract #0326