DUTCH GOG
The Dutch Gynaecological Oncology Group

Application form DGOG STUDY

Title project	DOMEC - Durvalumab and Olaparib in Metastatic or recurrent Endometrial Cancer trial
Name and contact details of project leader	Dr. Judith R Kroep Project leader J.R.Kroep@lumc.nl 071-526 3464 Drs. Cathalijne C.B. Post Study coordinator C.C.B.Post@lumc.nl 071-529 8586
Background (Max 10 lines / 100 words)	The prognosis of recurrent or metastatic endometrial cancer (EC) is poor. First line therapy consists of platinum-based chemotherapy or hormonal therapy. No standard subsequent-line therapy has been described. Tumors that are deficient in homologous recombination are most likely to benefit from PARP-inhibitors. In addition, programmed death-ligand-1 (PD-L1) blockers tends to work better in tumors with high mutational burden, such as POLE-mutated or mismatch repair deficient tumors. The combination of PARP and PD-L1 inhibition may result in a synergistic anti-tumor effect and has clear potential in the treatment of recurrent endometrial cancer. The DOMEC trial is designed to investigate this treatment combination among all molecular subgroups of EC.
Research question	The aim is to investigate the efficacy of the combination therapy of olaparib and durvalumab in terms of progression free survival. Secondary objectives are to determine objective response rate, overall survival, safety and predictive biomarkers.
Study design (Max 5 lines / 50 words)	The DOMEC trial is designed as a prospective, multi-center, single arm phase II study aiming to include 55 patients with advanced (recurrent, refractory or metastatic) endometrial cancer (all subtypes including carcinosarcoma) to investigate the efficacy of the combination therapy of olaparib tablets 300mg twice daily and durvalumab 1500mg IV every 4 weeks.
Power calculation (max 5 lines / 50 words)	Efficacy is defined as a median PFS of 6 months (compared to the estimated 30% PFS at 6 months without this treatment). 46 evaluable patients are needed to test the null hypothesis according to Simon's two-stage design. 55 patients will be entered into the trial (expected drop-out rate of 20%).
National or intern. study? Cooperation with which groups ?	National study initiated by the Dutch Gynaecological Oncology Group. The trial will be conducted across 8 gynaecological oncology centers in the Netherlands, including Amsterdam University Medical Center (UMC), Erasmus MC (Rotterdam), Leiden UMC, Maastricht UMC, Antoni van Leeuwenhoek (Amsterdam), Radboud UMC (Nijmegen), UMC Groningen and UMC Utrecht.
Funding	Partially sponsored by LUMC and co-funded by AstraZeneca.
Estimated period of inclusion and area of inclusion.	Total recruitment time is 30 months. Follow-up after inclusion of the last subject will be 6 months, resulting in a total study duration of 36 months.