**TP040/#1418**  
**PALBOCICLIB PLUS LETROZOLE COMBINATION AFTER PROGRESSION ON SECOND- LINE CHEMOTHERAPY FOR WOMEN WITH ER/PR-POSITIVE HIGH-GRADE SEROUS OR ENDOMETROID OVARIAN, FALLOPIAN TUBE OR PERITONEAL CANCER (LACOG 1018)**

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**Objectives**  
Limited treatment options are available for patients with ovarian high-grade serous carcinoma (HGSC) or endometroid carcinoma (EC) who progress after receiving chemotherapy for locoregional recurrence or metastatic disease. About 38–60% of these cases are ER/PR-positive. LACOG 1018 aims to evaluate the efficacy of palbociclib plus letrozole in this scenario.

**Methods**  
LACOG 1018 is a phase 2, single-arm, multicentric trial evaluating the efficacy of letrozole 2.5 mg/day plus palbociclib 125 mg/day for 21 days in 28-day cycles in patients with: 1) histologically proven ovarian HGSC or EC, fallopian tube or peritoneal cancer with locoregional recurrence (not amenable to curative therapy) or metastatic disease; 2) prior chemotherapy for locoregional recurrence or metastatic disease (≥ 1 platinum-based regimen and ≤ 3 prior chemotherapy regimens). Previous PARP inhibitors, bevacizumab and immunotherapy are allowed; 3) ER and/or PR-positive > 10% by immunohistochemistry (centrally confirmed); 4) EOCOG PS 0–2; 5) measurable disease by RECIST 1.1. The primary endpoint is PFS at 12 weeks. Secondary endpoints are overall survival, overall response rate, duration of response, clinical benefit rate, CA-125 response and time to progression, quality of life, safety, and predictive biomarkers of response and survival. Tumor evaluations are performed every 6 weeks until week 24. Sample size was calculated as 31 patients for the primary endpoint (90% power to detect 45% PFS at 12 weeks) and 39 patients for secondary endpoints considering 10% dropout. From Feb2020 – Jan2022, 43 patients were enrolled in 5 Brazilian centers. NCT03936270.

**Results**  
Trial in progress: no available results at submission.

**Conclusions**  
Trial in progress: no available conclusions at submission.

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**TP041/#1460**  
**THE CULTURE OF ADVANCED OR RECURRENT OVARIAN CANCER ORGANOIDs AND DRUG SCREENING**

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**TP042/#1526**  
**A SINGLE ARM PHASE II STUDY ON PEMBROLIZUMAB IN PRE-NEOPLASTIC HIGH GRADE HPV-RELATED VULVAR AND CERVICAL LESIONS**

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**Objectives**  
This is a single arm phase II trial evaluating Pembrolizumab as neoadjuvant treatment before surgical conization and/or partial or radical vulvectomy in patients with pre-neo plastic cervical and vulvar HPV-related high grade lesions. Primary objective of the study is to determine the efficacy of Pembrolizumab in leading histopathologic complete regression of cervical HSIL. Secondary objectives are: to determine the efficacy of Pembrolizumab in leading histopathologic complete regression of VIN 2–3; to evaluate the safety and tolerability of Pembrolizumab in patients with HPV-related pre-neo plastic vulvar and cervical lesions; to determine Pembrolizumab efficacy in the virologic clearance of HPV. Exploratory objectives are: to evaluate tissue immune responses to pembrolizumab in cervical and vulvar samples and to evaluate the influence of vaginal microbiome on Pembrolizumab response.
Methods Patients with histologically confirmed H-SIL and/or VIN 2–3 will be treated with Pembrolizumab 200 mg flat dose every 3 weeks for 5 cycles. Within 4 weeks from the last Pembrolizumab administration patients will be submitted to surgical conization (either cold knife conization or LEEP) and/or partial or radical vulvectomy. During the screening phase patients will receive blood and stool specimen’s collection. Genotyping for HPV will be performed at baseline, surgery and at safety follow up visit.

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission.

Results Trial in progress: there are no available results/conclusions at the time of submission.

Conclusions N/A