PHASE 2 RESULTS FROM THE LIO-1 STUDY (NCT04042116; ENGOT-GYN3/AGO/LIO): EFFICACY AND SAFETY OF LUCITANIB + NIVOLUMAB IN PATIENTS WITH ADVANCED GYNAECOLOGICAL MALIGNANCIES

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Abstracts

Introduction/Background LIO-1 (NCT04042116) assesses the combination of lucitanib, an oral anti-angiogenic, multitarget inhibitor administered using safety-based dose titration, and nivolumab, an inhibitor of programmed cell death receptor 1 (PD-1). Here, we present phase 2 study results of this combination in 4 advanced gynaecological malignancies.

Methodology LIO-1 enrolled patients with advanced, recurrent or metastatic endometrial cancer (EC), cervical cancer (CC), high-grade ovarian cancer (OC) or EC/OC with clear-cell histology (EOCC). Patients with EC, CC or EOCC received ≥1 prior platinum-based chemotherapies (CC, ≥ bevacizumab; EOCC, + taxane); patients with OC received ≥2 prior chemotherapies (including ≥1 platinum doublet). Patients received lucitanib at a starting dose of 6 mg QD plus intravenous nivolumab 480 mg every 28 days. Lucitanib dose could be escalated to 8 mg then 10 mg QD. The data cutoff was 14 April 2022.

Results Total treated was 124 patients; 31 (25.0%) patients are ongoing. At data cutoff, 32 (25.8%) patients escalated to lucitanib 8 mg and 20 (16.1%) to 10 mg. The confirmed best overall response rates at data cutoff were: EC cohort, 5/22 (22.7%); CC cohort, 12/46 (26.1%); OC cohort, 4/33 (12.1%); EOCC cohort, 6/23 (26.1%). Among EC-cohort patients, confirmed responses were reported for 2/5 patients who received prior PD-1 inhibitor (both were non-responders to prior PD-1 inhibitor). Among EC-cohort patients with confirmed responses that confirmed responses were observed in 3/14 with microsatellite stability and 2/3 with high instability. Grade ≥3 treatment-emergent adverse events (TEAEs) considered study-related were reported in 55 (44.4%) patients, with the most frequent being hypertension (n=30 [24.2%]), TEAEs leading to lucitanib dose reduction or discontinued occurred in 21 (16.9%) and 20 (16.1%) patients, respectively.

Conclusion Lucitanib + nivolumab displays anti-tumour activity in patients with advanced gynaecological malignancies, including clear-cell cancer. Effective dose titration resulted in manageable safety, similar to previous reports.

ANATOMY OF THE PRESACRAL REGION

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Introduction/Background The dissection of the presacral region is an integral component of multiple gynecologic cancer procedures such as lymph node staging, advanced staged disease and recurrence surgeries. The lack of knowledge of the anatomy can lead to severe complications such as vascular, ureteral, or nerve injuries that make up the complex region. To show anatomic concerns when surgeons dissect this region and to avoid severe complications we have developed a cadaveric video of the presacral region as well as the analysis and disposition of the more important anatomical landmarks.

Methodology We hereby demonstrate the anatomic data concerning the presacral region. Fifteen female cadaveric dissection models were evaluated. The presacral space was dissected to clearly defined anatomic landmarks. The midline of the region was marked from the promontory to its inferior edge, and measurements were taken from this imaginary line to key anatomical structures proximal to the presacral space. Special emphasis is placed on guiding the surgeon using still photographs and videos of cadaveric and live tissue dissection to optimize the understanding anatomy of the region.

Results The disposition of the following structures was analyzed in relation to the midline of the region: right ureter, right iliac vessels, left iliac vessels, specially left common iliac vein and hypogastric plexus. Additionally, middle sacral vessels were studied. The average distance between the midline of the region and right ureter was 3.1 cm, right common iliac vein 1.9 cm, right common iliac artery 2.6 cm, left common iliac vein 2.7 cm and left common iliac artery 3.4 cm. The location of the middle sacral vessels was quite variable.