LYMPHEDEMA AFTER VULVAR AND CERVICAL CANCER – IS IT TRULY A PROBLEM?

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Introduction/Background Secondary lymphedema remains a debilitating problem for cancer survivors. Yet, the incidence of this problem in Poland is unknown. We are lacking strategies to help raise awareness about secondary lymphedema. Furthermore, we need to develop plans for early detection and proper surveillance including all modalities of treatment.

As there is no national database for lymphedema after gynecological cancer in Poland, we aimed to investigate its incidence based on data from one gynecological oncology site.

Methodology We conducted a retrospective study on all women operated at the Department of Gynecology, Obstetrics and Oncological Gynecology, Bytom, Poland due to vulvar or cervical cancer between 2017 and 2022. A standard phone calls including questions about presence of lymphedema and subsequent treatment (no, physiotherapy, surgery) were made to each patient. The phone calls were made twice with 3-days gap in case of no response. All data were collected by a trained gyn intern.

Results We collected data from 90 women with vulvar cancer and 57 with cervical cancer. 30 out of 90 patients (33%) and 18 out of 57 patients (31.5%) had secondary lymphedema. Half of women with vulvar cancer and 2/3 of women with cervical cancer had lymphedema treatment. Types of lymphedema treatment included: compression therapy, manual lymphatic drainage.

Conclusion Our results indicate that 1/3 of women with vulvar and cervical cancer suffer from secondary lymphedema. In case of women with vulvar cancer only half of them seek or were offered treatment. The same situation is seen for 1/3 of women after cervical cancer surgery. We need strategies to better inform patients of possible sequelae of surgeries, so the patients search for help immediately after noticing the problem.

Disclosures No financial interest
Lymphodepletion chemotherapy (fludarabine 30 mg/m2/day for 4 days and cyclophosphamide 600 mg/m2/day for 3 days) will be followed by infusion of 1–10x10^9 ADP-A2M4CD8 T-cells. From Week 4 post-infusion, combination arm participants will receive nivolumab 480 mg every 4 weeks. Imaging will be performed at baseline, Weeks 8, 16, 24, then every 2 months ± 28 days until disease progression. Primary endpoint is objective response per RECIST v1.1 by independent review. Adverse events will be monitored, with participants followed for 15 years from T-cell infusion.

Conclusion SURPASS-3 is initiating in Q2 2023.

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**Abstract #84**

**TRIAL IN PROGRESS: A PHASE 2/3 STUDY OF NAVTEMADLIN AS MAINTENANCE THERAPY IN PATIENTS WITH ADVANCED OR RECURRENT ENDOMETRIAL CANCER (EC) WHO RESPONDED TO CHEMOTHERAPY (ENGOT-EN21 AND GOG-3089)**

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**Results NA**

**Conclusion NA**

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**Introduction/Background** Advanced/recurrent EC has poor prognosis with 5-year survival rate of ~17% (Colombo 2016; Siegel 2022). Maintenance treatment may improve and extend the durability of response to initial chemo/chemoimmunotherapy; novel agents are being tested in this setting to improve survival outcomes.

The tumor suppressor protein p53 can detect intracellular DNA damage and oncogenic aberrations leading to orderly apoptosis of tumorigenic cells. Mouse double minute 2 (MDM2), the key negative regulator of p53, is upregulated by some cancers to prevent p53 tumor suppressor function, while other cancers inactivate p53 by direct loss or mutation. MDM2 is upregulated in ~50% of EC patients (Jeczen 2007) due to loss of p14ARF, a critical modulator of intranuclear MDM2 levels.

Navtemadlin is a potent, selective, orally available MDM2 inhibitor that restores p53-mediated apoptosis in TP53WT tumors. The sensitivity of EC to genotoxic chemotherapy (Miller 2020) suggests susceptibility to p53-mediated apoptosis. Post-chemotherapy maintenance treatment with navtemadlin may provide a non-genotoxic way to maintain p53-driven activity and tumor cell control in the ~50% of EC patients who are TP53WT (Nakamura 2019).

KRT-232–118 is a Global 2-part Phase 2/3 study evaluating the safety and efficacy of navtemadlin as maintenance therapy in TP53WT advanced/recurrent EC patients following response to chemotherapy (EudraCT 2022–5002196–31; NCT03797831).

**Methodology** Eligible patients are adults with ECOG PS 0–1 who completed up to 6 cycles of chemotherapy excluding adjuvant/neoadjuvant therapy and achieved CR or PR per RECIST v1.1.

The open-label Phase 2 randomizes patients 2:1 to the RP3D vs placebo QD (Day 1–7/28-day cycle); stratification is by response and disease stage. Primary endpoint for Phase 3 is progression-free survival outcomes.

**Abstract #84 Figure 1 Study schema of KRT-232–118**