

**Abstract 991 Table 2** Risk of recurrence (One-dimension logistic regression model)

	OR (95% CI)	p-value
<b>Stage</b>		
T1a1	Reference category	-
T1a2	0.442 (0.067–1.756)	0.302
T1b1 ≤2cm	1.815 (0.867–4.160)	0.132
T1b1 >2cm	5.360 (1.890–15.017)	<b>0.001</b>
T1b2	7.897 (2.188–26.316)	<b>0.001</b>
T2	-	-
<b>Age at first diagnosis of cervical cancer [years]</b>		
	0.956 (0.895–1.019)	0.175
<b>Histological type</b>		
Adeno	Reference category	-
Adenosquamous	1.228 (0.270–4.087)	0.759
Squamous	0.841 (0.440–1.696)	0.611
Other	19.038 (2.917–154.774)	<b>0.002</b>
<b>Largest size of the tumor [mm]</b>		
	1.057 (1.027–1.088)	<b>&lt;0.001</b>
<b>Type of cervical procedure</b>		
Conization	Reference category	-
Laparoscopic radical trachelectomy	0.652 (0.102–2.315)	0.571
Radical abdominal trachelectomy	1.821 (0.927–3.524)	0.076
Radical vaginal trachelectomy	0.968 (0.348–2.318)	0.945
Robotic radical trachelectomy	-	-
Simple vaginal trachelectomy	1.034 (0.295–2.824)	0.952

was observed in tumours  $\geq 2$  cm in comparison to smaller tumours (19.4% vs. 5.7%;  $p < 0.001$ ). The most frequent locations of recurrence were cervix (53%) and pelvic nodes (22%). Median DFI for invasive recurrence reached 18 months.

**Conclusion\*** Data from the real life practice showed that FST in cervical cancer patients is safe in patients with HPV related tumours smaller than 2 cm. In such tumours conization represents sufficient procedure with satisfactory pregnancy outcomes. Surprisingly less than half of patients attempt to conceive after treatment.

## Miscellaneous

### 55 SGNTUC-019: PHASE 2 BASKET STUDY OF TUCATINIB AND TRASTUZUMAB IN SOLID TUMORS WITH HER2 ALTERATIONS: UTERINE AND CERVICAL CANCER COHORTS

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**Introduction/Background\*** Tucatinib, a highly selective HER2-directed tyrosine kinase inhibitor with minimal EGFR inhibition, is approved for use in combination with trastuzumab and capecitabine in patients with breast cancer who have received anti-HER2-based regimens in the metastatic setting. In xenograft models of HER2-overexpressed/amplified (HER2

+) and HER2-mutated tumors, dual targeting with tucatinib and trastuzumab showed superior activity to either agent alone.

The prognosis of locally-advanced unresectable or metastatic (LAUM) cervical and uterine cancer remains poor. HER2 amplification/overexpression and mutations occur in up to 21% and 80% of cervical and uterine cancers, respectively.

**Methodology** SGNTUC-019 (NCT04579380) is an open-label, international Phase 2 basket study evaluating tucatinib and trastuzumab in adult patients with LAUM HER2+ or HER2-mutated solid tumors. Multiple disease- and HER2 alteration-specific cohorts are being enrolled, including HER2+ cervical and uterine cancer cohorts. Patients will receive tucatinib 300 mg orally twice daily and trastuzumab 8 mg/kg IV on Cycle 1 Day 1 and 6 mg/kg q21 days from Cycle 2 Day 1

HER2+ cervical and uterine cancer cohorts will enroll 12 patients each. If  $\geq 2$  responses are observed in a cohort, it will be expanded to 30 patients. Patients with HER2-mutated cervical and uterine cancers will enroll in a cohort of 30 patients for all solid tumor types.

Eligible patients must have progressed on or after the last systemic therapy, with platinum-based therapy  $\pm$  bevacizumab required in patients with metastatic cervical cancer. Patients must have ECOG PS  $\leq 1$ , adequate organ function, and have not received HER2-directed therapy; patients with uterine serous carcinoma may have received trastuzumab. HER2 alterations can be demonstrated by HER2 overexpression/amplification in tumor tissue by prior IHC/ISH, or by HER2 amplification/mutation in a prior or on-study NGS assay of ctDNA or prior tissue NGS assay.

The primary endpoint is confirmed ORR per investigator. Disease control rate, duration of response, PFS, and OS are the secondary endpoints. Disease assessments per RECIST 1.1 will occur q6 weeks for 24 weeks, then q12 weeks. QoL will be evaluated q2 cycles using EQ-5D-5L.

**Result(s)\*** Not applicable.

**Conclusion\*** Enrollment in US began in Dec 2020; EU and Asia sites will be opened.

### 69 SURGICAL AND MEDICAL TREATMENTS FOR UTERINE PECOMAS

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**Introduction/Background\*** Perivascular epithelioid cell tumors (PEComas) are rare mesenchymal neoplasms. Uterine PEComa is extremely rare and only limited evidence is still available.

**Methodology** This is a single-center retrospective study. Charts of consecutive patients who had treatment (from 01/01/2010 to 12/31/2020) for newly diagnosed uterine PEComas were retrieved. Five-year survival outcomes were assessed using Kaplan-Meier and Cox proportional hazard models.

**Result(s)\*** Data of 23 patients with newly diagnosed PEComas were analyzed. Mean (SD) patients' age was 52 (14) years. Twenty-two patients had a surgical cytoreductive attempt. In one case surgery was not performed due to the presence of an extra-abdominal spread. Overall, seven (30%) patients had disease outside the uterus at the time of surgery. Complete cytoreduction (no macroscopic residual tumor) was achieved in 19 patients. Complete cytoreduction was not completed in