**A Phase 3 Study of Pembrolizumab (Pembro) + Concurrent Chemoradiotherapy (CCRT) for High-Risk Locally Advanced Cervical Cancer (LACC): Safety Findings**

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**Purpose/Objective(s):** In ENGOT-cx11/GOG-3047/KEYNOTE-A18 (NCT 04221945), pembro + CCRT improved PFS (HR = 0.70 [95% CI = 0.55‒0.89]; P = 0.0020) and showed a favorable trend in OS (HR = 0.73 [95% CI = 0.49‒ 1.07]) vs placebo (pbo) + CCRT in high-risk LACC at interim analysis 1 (IA1). Here, we report IA1 safety data.

**Materials/Methods:** Patients (pts) with previously untreated, high-risk LACC (FIGO 2014 stage IB2‒IIB node-positive or stage III‒IVA) were randomized 1:1 to 5 cycles of pembro 200 mg or pbo Q3W + CCRT, then 15 cycles of pembro 400 mg or pbo Q6W. CCRT included 5 cycles (optional 6th dose) of cisplatin 40 mg/m2 QW + EBRT followed by brachytherapy. Safety was evaluated in all randomized and treated pts.

**Results:** Of 1060 randomized pts, 1058 were included in the safety analysis. At data cutoff (Jan 9, 2023), median follow-up was 17.9 mo. AE rates were similar between the treatment arms (see the Table). AEs were more common during the pembro + CCRT combination therapy phase vs pembro monotherapy phase. Exposure-adjusted AE rates generally decreased after 3 mo; hypothyroidism was most common between 3-6 mo with pembro + CCRT. Event rates for genitourinary AEs were < 10.0 events per 100 person-months of exposure during any period.

**Conclusion:** Pembro + CCRT had manageable safety that was consistent with the known profiles of pembro monotherapy and chemoradiotherapy. Most AEs occurred during the combination therapy phase. Abstract.

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