Cervical cancer

40 INNOVATV 301/ENGOT-CX12/GOG-3057: TISOTUMAB VEDOTIN VS INVESTIGATOR'S CHOICE CHEMO IN SECOND- OR THIRD-LINE RECURRENT OR METASTATIC CERVICAL CANCER

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Introduction/Background* Doublet chemotherapy (paclitaxel plus either platinum or topotecan) with bevacizumab (if eligible) is recommended for first-line treatment of recurrent or metastatic cervical cancer (r/mCC; Tewari 2014). In the second-line setting, there are limited data for available treatment options.

Tisotumab vedotin (TV) is an investigational antibody-drug conjugate directed to tissue factor. In the phase 2 pivotal trial (innovaTV 204/ENGOT-cx6/GOG-3023) in r/mCC patients with disease progression on or after chemotherapy, TV demonstrated clinically meaningful and durable activity (objective response rate [ORR]: 24%; median duration of response [DOR]: 8.3 months) with a manageable and tolerable safety profile. Most adverse events associated with TV were mild to moderate. These findings support further investigation of TV in patients with r/mCC who progress on first-line treatment options.

Methodology innovaTV 301/ENGOT-cx12/GOG-3057 (NCT04697628) is a global, randomized, open-label, phase 3 trial evaluating efficacy and safety of TV in patients with previously treated r/mCC. Eligible patients must be ≥18 years, have r/mCC, and have progressed after receiving 1–2 prior lines of therapy (either standard of care systemic chemotherapy doublet or platinum-based therapy with bevacizumab, if eligible).

Approximately 482 patients will be randomized 1:1 to receive 21-day cycles of TV (2.0 mg/kg IV once every 3 weeks) or investigator's choice of chemotherapy: topotecan, vinorelbine, gemcitabine, irinotecan, or pemetrexed. The primary endpoint is overall survival. Key secondary endpoints are progression-free survival, ORR, time to response, DOR, safety, and quality of life outcomes. The study is enrolling and will have sites in the USA, Europe, Japan, Latin America, Taiwan, Singapore, and South Korea.

Result(s)* Not applicable for trial in progress

Conclusion* Not applicable for trial in progress

57 ALPELISIB FOR RECURRENT PIK3CA-MUTATED RECURRENT CERVCIAL CANCER

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Introduction/Background* Advanced/recurrent cervical cancer has limited therapeutic options, with a median progression-free survival (PFS) after the failure of systemic treatments ranging between 3.5 and 4.5 months. Here, we reported our preliminary experience in the use of BYL719 (alpelisib) in advanced/recurrent cervical cancer after failure of at least 2 lines of treatment.

Methodology The Fondazione IRCCS Istituto Nazionale dei Tumori di Milano (Italy) approved this prospective investigation. From 04/01/2020 to 09/01/2020, 17 consecutive patients with recurrent cervical cancer underwent next generation sequencing (NGS) to assess the presence of PIK3CA mutation/alteration.

Result(s)* Overall, 17 patients were tested for PIK3CA mutation/alteration. PIK3CA mutation was detected in seven (41%) patients. Six patients were included in the study; one patient was diagnosed with a synchronous tumor during the screening phase. All patients had been treated with at least 2 previous lines of systemic treatment: 3 patients received >2 prior lines of treatment in the recurrent or metastatic setting; 60% had received prior bevacizumab in combination with chemotherapy. All patients started alpelisib at the daily dosage of 300 mg. Investigator-assessed confirmed objective response rate (ORR) was 33%. The disease control rate (DCR) was 100%. According to the RECIST 1.1, two patients had a partial response (PR), and four patients had stable disease (SD). No complete response was observed. The mean duration of response (DOR) was 6.6 (SD 3.75) months; four patients had PR lasting for >6 months. One patient stopped the treatment at 0.82 months due to the onset of a grade 2 adverse event (AE) (skin rash). Grade 3 treatment-related AEs included: lymphoedema (n=1, 20%) and rash (n=1, 20%). No treatment-related grade 4–5 AEs occurred.

Conclusion* Further trials are needed to assess the safety and effectiveness of alpelisib in PIK3CA-mutated recurrent/advanced cervical cancer

66 RADICAL TRACHELECTOMY. EXPERIENCE IN KAIOR

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Introduction/Background* Radical trachelectomy with pelvic lymphadenectomy, originally described by Dargent et al. in 1988 became a new treatment option for young patients in the world with early invasive cervical cancer who want to maintain their fertility. Recent data indicate that cancer outcomes after radiation therapy are comparable to those after standard radical hysterectomy .Fertility-sparing radical trachelectomy was revolutionary when it first appeared. This procedure now allows patients to survive cancer and save uterus for future bearing of the child. Initially, they approached him as a vaginal procedure with laparoscopic evaluation. This approach is comparable to type B or modified radical hysterectomy, but with greater limited resection of parametrium.

Methodology statistical analysis

Result(s)* Since 2013, radical trachelectomy has been performed at KazIOR. From 2013 to 2021, 8 operations were performed, 7 of them by abdominal access, 3 by laparoscopic approach. 6 (75%) of the patients had stage 1 in 1 from 2 to