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Phase III study of camrelizumab plus famitinib versus platinum-based chemotherapy as first-line therapy for recurrent or metastatic cervical cancer

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Background

The standard first-line therapy for recurrent or metastatic cervical cancer (R/M CC) is platinum-based chemotherapy (chemo), with/without bevacizumab or immunotherapy. However, chemo-related toxicity remains a challenge. We aimed to explore the feasibility of a chemo-free approach. In a prior phase 2 study, camrelizumab (CAM, an anti-PD-1 mAb) and famitinib (FAM, a multitarget receptor TKI) showed improved antitumor activity vs CAM alone or investigator's choice of chemo in patients (pts) with pre-treated R/M CC (JCO 2025). In this context, we designed this study to confirm the efficacy and safety of CAM plus FAM vs platinum-based chemo with/without bevacizumab in the first-line setting.

Methods

In this multicenter, phase 3 study, pts were randomized (1:1) to receive either CAM (200 mg, iv, Q3W) plus FAM (20 mg, po, qd) or investigator's choice of chemo (paclitaxel + cisplatin/carboplatin, with/without bevacizumab). Randomization was stratified by PD-L1 CPS (≥1 vs <1) and prior use of platinum (yes vs no). Primary endpoint was PFS per RECIST version 1.1 as assessed by blinded independent central review (BICR) and OS. The planned interim analysis was done after 283 PFS events and 204 deaths occurred in the ITT population.

Results

As of data cutoff (Jun 10, 2025), 443 pts were randomly assigned to CAM + FAM (N=220) or chemo (N=223). Median follow-up was 19.3 mo. 93.0% of pts had PD-L1 CPS ≥1, and 70.4% received prior platinum. PFS per BICR was significantly improved with CAM + FAM vs chemo (median 11.1 mo [95% CI 8.4-13.6] vs 7.5 mo [95% CI 6.3-8.3]; HR 0.68 [95% CI 0.53-0.86]; 1-sided p=0.0007). OS was significantly prolonged with CAM + FAM vs chemo (median 34.4 mo [95% CI 29.6-NR] vs 23.4 mo [19.5-28.2]; HR 0.65 [95% CI 0.49-0.86]; 1-sided p=0.0012). Grade ≥3 TRAEs occurred in 87.3% with CAM + FAM and 67.1% with chemo. TRAE led to discontinuation of any treatment in 13.6% with CAM + FAM and 6.6% with chemo.

Conclusions

This chemo-free regimen of CAM plus FAM significantly prolongs PFS and OS compared with platinum-based chemo with/without bevacizumab as first-line treatment in pts with R/M CC, with a tolerable safety profile.

Clinical trial identification

NCT04906993; Release date: May 26, 2021.

Legal entity responsible for the study

Jiangsu Hengrui Pharmaceuticals Co., Ltd.

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Disclosure

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