Background Cervical cancer is the fourth most common cancer affecting women globally, but treatment options and outcomes for patients with recurrent or metastatic disease remain limited. Zimberelimab is a novel, fully human anti-PD-1 monoclonal antibody with high affinity and selectivity for PD-1. The objective of this study (ClinicalTrials.gov identifier: NCT03972722) was to evaluate zimberelimab, a novel, anti-programmed cell death protein 1 monoclonal antibody, in patients with programmed death ligand-1-positive recurrent or metastatic cervical cancer that had progressed after first- or subsequent-line platinum-containing standard chemotherapy. Further investigation of zimberelimab in patients with cervical cancer is warranted.

Methods In this single-arm, phase II study, eligible patients in 27 Chinese sites were assigned to receive intravenous zimberelimab 240 mg as monotherapy every 2 weeks until confirmed disease progression, death, intolerable adverse effects, or withdrawal from the study. The primary endpoint was the objective response rate (ORR) assessed per Response Evaluation Criteria in Solid Tumors (version 1.1) by an independent review committee. Secondary endpoints included duration of response (DoR), disease control rate (DCR), progression-free survival (PFS), overall survival (OS), and safety.

Results Ninety participants were included in the full analysis set, with a median follow-up of 11.5 months. Complete and partial responses were achieved by 4 and 21 patients, respectively, corresponding to an ORR of 27.8% (95% confidence interval [CI], 18.85 to 38.22; \( P < .0001 \) vs historical controls). Median OS and DoR were not reached during the study: 12-month OS rates were 84% (95% CI, 58 to 95). Median PFS was 3.7 months and the 12-month PFS rate was 15% (95% CI, 2 to 42). Treatment-related adverse events (TRAEs) occurred in 78.1% of participants, with hypothyroidism (25.7%) and anemia (19.0%) being the most frequently reported. Grade \( \geq 3 \) TRAEs occurred in 22.9% of participants.

Conclusions Zimberelimab monotherapy demonstrated durable antitumor activity and an acceptable safety profile in patients with recurrent or metastatic cervical cancer that had progressed after first- or subsequent-line platinum-containing standard chemotherapy. Further investigation of zimberelimab in patients with cervical cancer is warranted.

Trial Registration NCT03972722

Ethics Approval This phase II, single-arm, open-label study (NCT03972722) enrolled patients at 27 sites in China. The study was approved by the ethics committee at each participating center and was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice for Drug Trials. All participants provided signed informed consent before any study procedure.