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Endometrial Hyperplasia, Endometrial Intra-epithelial Neoplasia, and Endometrial Cancer

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Phase 3 study (Study 309/KEYNOTE-775) of lenvatinib plus pembrolizumab vs treatment of physician's choice in advanced endometrial cancer: Japanese subset

Mayu Yunokawa,¹ Keiichi Fujiwara²
¹Cancer Institute Hospital of JFCR, Tokyo, Japan (mayu.yunokawa@jfc.or.jp)

²Saitama Medical University International Medical Center, Hidaka, Japan

Objective: The primary objectives of Study 309/KEYNOTE-775 were to demonstrate that lenvatinib + pembrolizumab was superior to treatment of physician's choice (TPC) in improving PFS and OS in patients with advanced endometrial cancer (aEC). We present results for the overall population and Japanese patients.

Methods: Patients were randomized to lenvatinib 20 mg/d + pembrolizumab 200 mg/Q3W or TPC (doxorubicin 60 mg/m² Q3W or paclitaxel 80 mg/m² QW [3-weeks-on; 1-week-off]). Randomization was stratified by mismatch repair status (proficient vs. deficient). Patients had confirmed advanced/recurrent/metastatic EC with progression after 1 prior platinum-based regimen. Tumors were assessed by BICR per RECIST v1.1.

Results: The 827 patients were enrolled including 104 Japanese patients. In the overall population, lenvatinib + pembrolizumab improved overall survival (OS) and progression-free survival (PFS) versus TPC in proficient mismatch repair (pMMR) and all-comer patients (OS hazard ratio [HR], [95% confidence interval; CI]: pMMR, 0.68 [0.56–0.84], p=0.0001; all-comers, 0.62 [0.51–0.75], p<0.0001; PFS HR [95% CI]: pMMR, 0.60 [0.50–0.72], p<0.0001; all comers, 0.56 [0.47–0.66], p<0.0001). Among Japanese patients, HRs (95% CI) for OS were 0.74 (0.41–1.34) for pMMR patients and 0.59 (0.33–1.04) for all-comers. HRs (95% CI) for PFS were 1.04 (0.63–1.73) for pMMR patients and 0.81 (0.50–1.31) for all-comers. Among Japanese patients, incidence of grade ≥3 adverse events was 90.4% for pembrolizumab and 82.4% for TPC.

Conclusion: Lenvatinib + pembrolizumab showed clinically meaningful improvements in efficacy outcomes versus TPC in patients with aEC. Although the study was not designed to demonstrate superiority in Japanese patients, this subgroup analysis suggested favorable efficacy of lenvatinib + pembrolizumab. Lenvatinib + pembrolizumab is a potential treatment option for Japanese patients with aEC.