# Efficacy and Safety of Pembrolizumab or Pembrolizumab Plus Chemotherapy vs Chemotherapy Alone for Patients With First-line, Advanced Gastric Cancer: The KEYNOTE-062 Phase 3 Randomized Clinical Trial

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## Abstract

IMPORTANCE Safe and effective therapies for untreated, advanced gastric/gastroesophageal junction (G/GEJ) cancer remain an unmet need.

OBJECTIVE To evaluate the antitumor activity of pembrolizumab, pembrolizumab plus chemotherapy, or chemotherapy alone in patients with untreated, advanced G/GEJ cancer with programmed cell death ligand l(PD-L1) combined positive score (CP5) of lor greater.

DESIGN, SETTING. AND PARTICIPANTS The phase 3 KEYNOTE -062 randomized, controlled, partially blinded interventional trial enrolled 763 patients with untreated, locally advanced/unresectable or metastatic G/GEJ cancer with PD-L1CPS of lor greater from 200 centers in 29 countries between September 18, 2015, and May 26, 2017.

INTERVENTIONS Patients were randomized 1:1:1to pembrolizumab 200 mg, pembrolizumab plus chemotherapy (cisplatin 80 mg/m2/d on day 1plus fluorouracil 800 mg/m2/d on days 1 to 5 or capecitabine 1000 mg/m2twice daily), or chemotherapy plus placebo, every 3 weeks.

MAIN OUTCOME ABD MEASURES Primary end points were overall survival (OS) and progression - free survival (PFS) in patients with PD-L1CPS of lor greater or 10 or greater. RE.5).K.Ts A total of 763 patients were randomized to pembrolizumab (n = 256), pembrolizumab plus chemotherapy (n = 257), or chemotherapy (n = 250). The median (range) age of all patients in the study cohort was 62 (20-87) years; 554 of 763 (72.6%) were men. At final analysis, after a median (range) follow-up of 29.4 (22.0-41.3) months, pembrolizumab was noninferior to chemotherapy for OS in patients with CPS of lor greater (median, 10.6 vs 11.1months; hazard ratio [HR], 0.91; 99.2% CI, 0.69-1]8). Pembrolizumab monotherapy was not superior to chemotherapy in patients with CPS of lor greater. Pembrolizumab prolonged OS vs chemotherapy in patients with CPS of 10 or greater (median, 17.4 vs 10.8 months; HR, 0.69; 95% CI, 0.49-0.97), but this difference was not statistically tested. Pembrolizumab plus chemotherapy was not superior to chemotherapy for OS in patients with CP5 of lor greater (12.5 vs 11.1 months; HR, 0.85; 95% CI, 0.70-1.03; P =.05) or CP5 of 10 or greater (12.3 vs 10.8 months; HR, 0.85; 95% CI, 0.62-1.17; P =.16) or for PFS in patients with CPS of lor greater (6.9 vs 6.4 months; HR, 0.84; 95% Cl, 0.70-1.02; P =.04). Grade 3 to 5 treatment-related adverse event rates for pembrolizumab, pembrolizumab plus chemotherapy, and chemotherapy were 17%, 73%, and 69%, respectively.

CONCLUSIONS AND RELEVANCE This phase 3 randomized clinical trial found that among patients with untreated, advanced G/GEJ cancer, pembrolizumab was noninferior to chemotherapy, with fewer adverse events observed. Pembrolizumab or pembrolizumab plus chemotherapy was not superior to chemotherapy for the OS and PFS end points tested.

## Palabras clave

**KeyWords Plus:**DOUBLE-BLIND; FLUOROURACIL; THERAPY; CISPLATIN; DOCETAXEL

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