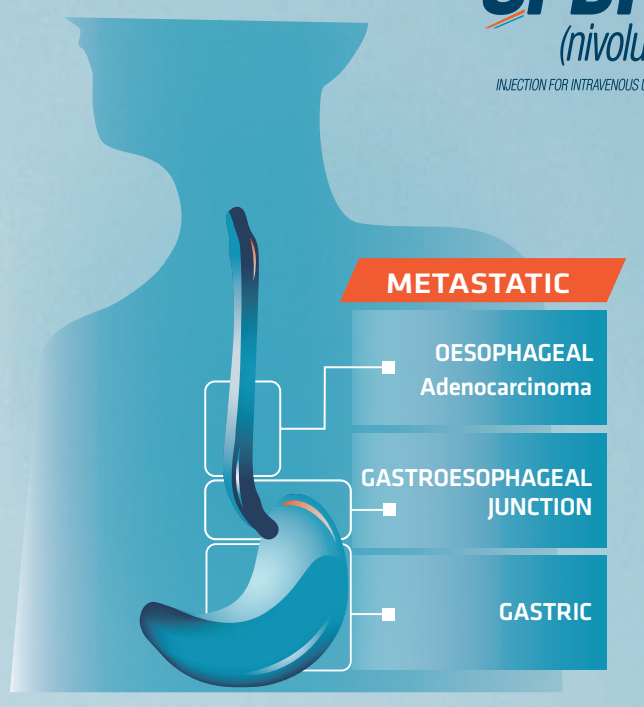
OPDIVO® (nivolumab) + FOLFOX or CapeOX: Superior overall survival* in a trial with metastatic gastric, GEJ, and oesophageal adenocarcinomas[1,2]

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL



INDICATION

OPDIVO, in combination with fluoropyrimidine- and platinum-based chemotherapy, is indicated for the treatment of patients with unresectable HER2 negative advanced or metastatic gastric cancer, gastroesophageal junction cancer, or oesophageal adenocarcinoma.

OPDIVO (10 mg/mL) is an injection for IV use.[1]

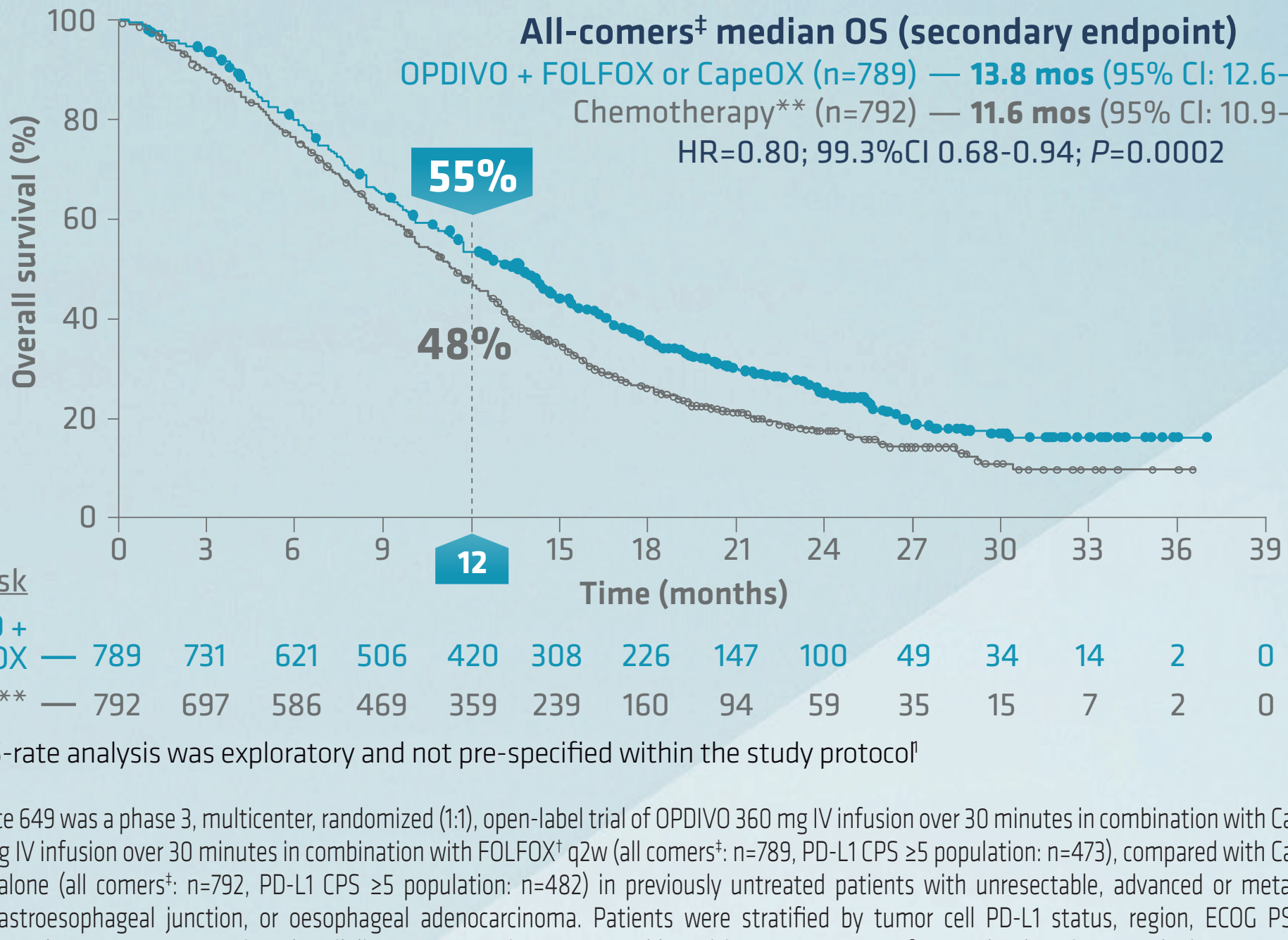
OPDIVO IS THE ONLY 1L I-O THERAPY[1,2]:

APPROVED[¶] REGARDLESS OF PD-L1 EXPRESSION IN 3 GASTROESOPHAGEAL TUMOR TYPES

STUDIED IN A PHASE 3 TRIAL WITH FOLFOX AND CAPEOX[#]

TO OFFER Q2W AND Q3W DOSING TO MATCH YOUR CHEMO PREFERENCES[¶#]

In 1L patients with metastatic GC, GEJC, and EAC OPDIVO + FOLFOX or CapeOX: The only I-O regimen with 55% of patients alive at 1 year[1,2]



All-comers‡ median OS (secondary endpoint)

OPDIVO + FOLFOX or CapeOX (n=789) — **13.8 mos** (95% CI: 12.6–14.6)

Chemotherapy** (n=792) — **11.6 mos** (95% CI: 10.9–12.5)

HR=0.80; 99.3%CI 0.68-0.94; *P*=0.0002

- The 12-month OS-rate analysis was exploratory and not pre-specified within the study protocol[‖]

Trial design: Checkmate 649 was a phase 3, multicenter, randomized (1:1), open-label trial of OPDIVO 360 mg IV infusion over 30 minutes in combination with CapeOX q3w, or OPDIVO 240 mg IV infusion over 30 minutes in combination with FOLFOX[†] q2w (all comers[‡]: n=789, PD-L1 CPS ≥5 population: n=473), compared with CapeOX q3w or FOLFOX q2w alone (all comers[‡]: n=792, PD-L1 CPS ≥5 population: n=482) in previously untreated patients with unresectable, advanced or metastatic non-HER2+ gastric, gastroesophageal junction, or oesophageal adenocarcinoma. Patients were stratified by tumor cell PD-L1 status, region, ECOG PS, and chemotherapy regimen, and treatment was continued until disease progression, unacceptable toxicity, or up to 2 years for IO only. The primary endpoints, assessed in patients with PD-L1 CPS ≥5, were PFS[§] and OS. Secondary endpoints included OS in patients with PD-L1 CPS ≥1 and in all comers,[‡] and ORR[§] in all comers.[‡] Since OS in the PD-L1 CPS ≥5 population was statistically significant, OS in PD-L1 CPS ≥1, followed by OS in all comers,[‡] were tested hierarchically.[1,2]

Dual primary endpoints in the PD-L1 CPS ≥5 population (n=955)[1]

- **mOS: 14.4 mos** (95% CI: 13.1–16.2) with OPDIVO + FOLFOX or CapeOX vs **11.1 mos** (95% CI: 10.0–12.1) with chemotherapy** alone (HR=0.71; 98.4%CI 0.59-0.86; P<0.0001)
- **mPFS: 7.7 mos** (95% CI: 7.0–9.2) with OPDIVO + FOLFOX or CapeOX vs **6.0 mos** (95% CI: 5.6–6.9) with chemotherapy** alone (HR=0.68; 98%CI 0.56-0.81; P<0.0001)

*OPDIVO + FOLFOX or CapeOX vs FOLFOX or CapeOX alone.[1] [†]mFOLFOX6 (leucovorin, fluorouracil, and oxaliplatin) regimen was given in Checkmate 649.[1] [‡]All comers refers to all randomized patients in Checkmate 649.[1] [§]Assessed using blinded independent central review (BICR).[1] [‖]Based on confirmed response.[1] [¶]In combination with fluoropyrimidine- and platinum-containing chemotherapy.[1] [#]In 1L patients with metastatic gastric, GEJ, and oesophageal adenocarcinomas non-HER2+.[1] **FOLFOX or CapeOX.[1]

1L=first line; CapeOX=capecitabine and oxaliplatin; chemo=chemotherapy; CI=confidence interval; CPS=combined positive score; EAC=oesophageal adenocarcinoma; ECOG PS=Eastern Cooperative Oncology Group Performance Status; FOLFOX=leucovorin, fluorouracil, and oxaliplatin; GC=gastric cancer; GEJ=gastroesophageal junction; GEJC=GEJ cancer; HER2=human epidermal growth factor receptor 2; HR=hazard ratio; IV=intravenous; I-O=immuno-oncology; K-M=Kaplan-Meier; mo=month; mOS=median OS; mPFS=median PFS; ORR=overall response rate; OS=overall survival; PD-L1=programmed death ligand 1; PFS=progression-free survival; q2w=every 2 weeks; q3w=every 3 weeks.

Flexible dosing with fluoropyrimidine- and platinum-containing chemotherapy

OPDIVO 240 mg q2w (30 minute IV infusion) **with q2w chemo**

OR

OPDIVO 360 mg q3w (30 minute IV infusion) **with q3w chemo**

Continue treatment until disease progression, unacceptable toxicity, or up to 2 years
OPDIVO is administered over 30-60 minutes as an intravenous infusion

In the Checkmate 649 study design, in the OPDIVO + chemotherapy arm, patients who discontinued chemotherapy were permitted to receive OPDIVO monotherapy at 240 mg q2w, 360 mg q3w, or 480 mg q4w[†] up to 2 years after treatment initiation[1]*

References: 1.OPDIVO HSA Approved Prescribing information Feb 2022. 2. Moehler M, Shitara K, Garrido M, et al. Nivolumab plus chemotherapy versus chemotherapy as first-line treatment for advanced gastric cancer/gastroesophageal junction cancer/oesophageal adenocarcinoma: first results of the CheckMate 649 study. Presentation at ESMO 2020. Presentation LBA6.

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