KEYNOTE-859: a Phase III study of pembrolizumab plus chemotherapy in gastric/gastroesophageal junction adenocarcinoma

Authors

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Trial registration no:
NCT03675737

Primary objectives

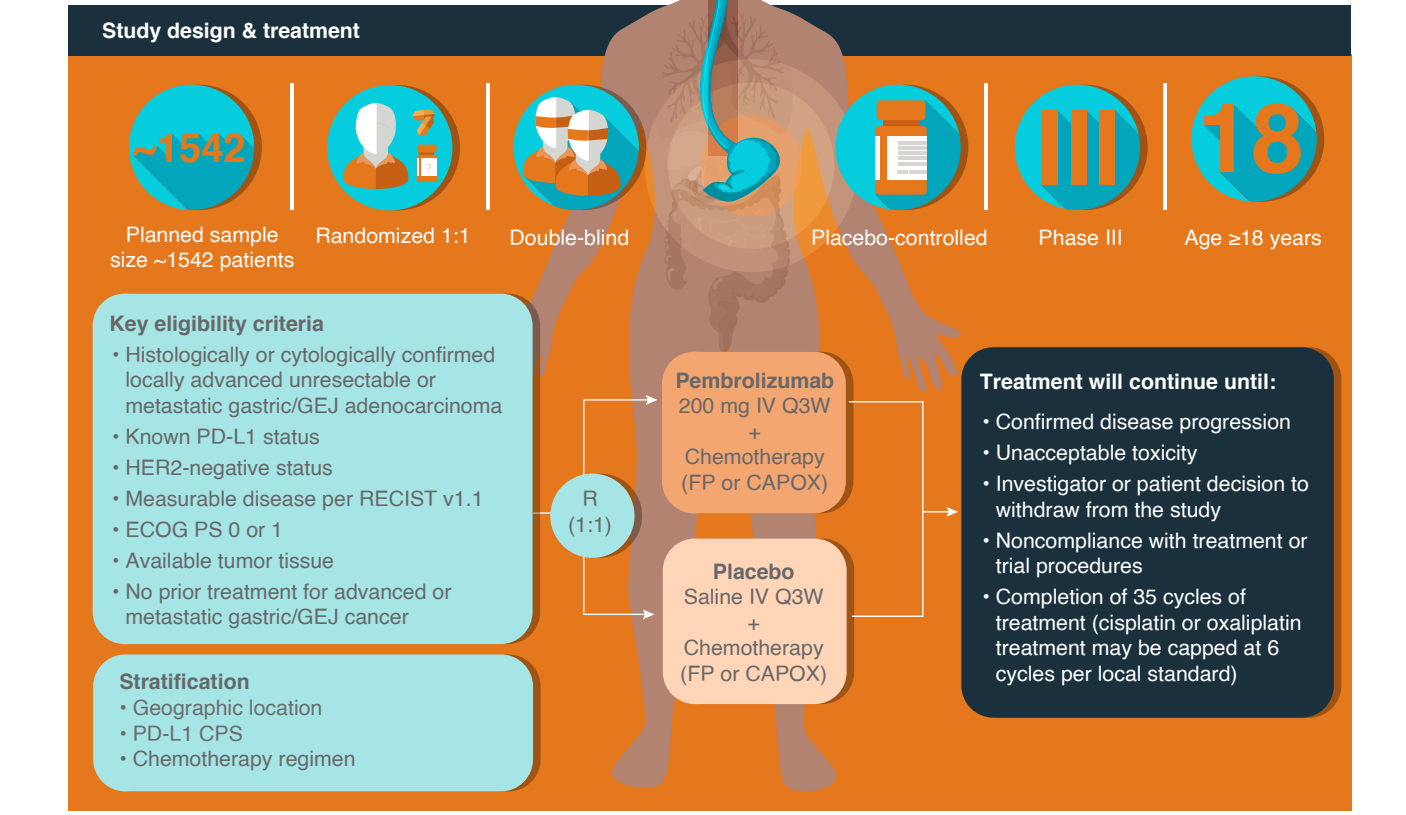
Primary objective

To compare OS between pembrolizumab plus chemotherapy and placebo plus chemotherapy

Secondary key objectives

- To compare PFS assessed per RECIST v1.1 by BICR between pembrolizumab plus chemotherapy and placebo plus chemotherapy
- To compare ORR assessed per RECIST v1.1 by BICR between pembrolizumab plus chemotherapy and placebo plus chemotherapy
- To compare DOR assessed per RECIST v1.1 by BICR between pembrolizumab plus chemotherapy and placebo plus chemotherapy
- To evaluate the safety and tolerability of pembrolizumab plus chemotherapy and of placebo plus chemotherapy

Study design & treatment



Key eligibility criteria

- Histologically or cytologically confirmed locally advanced unresectable or metastatic gastric/GEJ adenocarcinoma
- Known PD-L1 status
- HER2-negative status
- Measurable disease per RECIST v1.1
- ECOG PS 0 or 1
- Available tumor tissue
- No prior treatment for advanced or metastatic gastric/GEJ cancer

Stratification

- Geographic location
- PD-L1 CPS
- Chemotherapy regimen

R (1:1)

Pembrolizumab
200 mg IV Q3W
+
Chemotherapy
(FP or CAPOX)

Placebo
Saline IV Q3W
+
Chemotherapy
(FP or CAPOX)

Treatment will continue until:

- Confirmed disease progression
- Unacceptable toxicity
- Investigator or patient decision to withdraw from the study
- Noncompliance with treatment or trial procedures
- Completion of 35 cycles of treatment (cisplatin or oxaliplatin treatment may be capped at 6 cycles per local standard)

Outcome measures/end points

Primary end point:
OS (defined as the time from randomization to death from any cause)

Secondary end points:
PFS, ORR, DOR, safety and tolerability

Exploratory end points:
HRQoL (assessed using EORTC QLQ-C30, EORTC QLQ-STO22, and EQ-5D-5L), PFS and ORR per iRECIST, and molecular biomarkers

Glossary

BICR: Blinded independent central review; CAPOX: Capecitabine plus oxaliplatin; CPS: Combined positive score; DOR: Duration of response; ECOG PS: Eastern Cooperative Oncology Group performance status; EORTC QLQ-C30: European Organisation for the Research and Treatment of Cancer Quality of Life Question naire Core 30; EORTC QLQ-STO22: European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire–Stomach; EQ-5D-5L: EuroQol 5-dimension, 5-level; FP: 5-fluorouracil plus cisplatin; GEJ: Gastroesophageal junction; HER2: Human epidermal growth factor receptor 2; HRQoL: Health-related quality of life; iRECIST: modified RECIST version 1.1 for immune-based therapies; IV: Intravenously; ORR: Objective response rate; OS: Overall survival; PD-L1: Programmed death ligand 1; PFS: Progression-free survival; Q3W: Every 3 weeks; RECIST: Response Evaluation Criteria in Solid Tumors.