VIRTUAL ESMO congress 2020

1447P

S-1 maintenance therapy in non-Asian patients with advanced, Her-2 negative esophagogastric adenocarcinoma – First results of the international MATEO trial initiated by the AIO

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Background

Platinum-fluoropyrimidine-based polychemotherapy is standard for advanced Her-2 negative esophagogastric adenocarcinoma. The optimal duration of treatment is unknown; prolonged application of platinum compounds leads to side effects with questionable overall survival (OS) benefit.

Methods

MATEO is an international, multicenter, randomized phase II trial exploring the role of fluoropyrimidine maintenance therapy with S-1 (tegafur/gimeracil/oteracil) compared with prolonged polychemotherapy. Patients without progression after 12 weeks of platinum-based induction therapy were randomized in a 2:1 allocation to receive S-1 (Arm A) or to continue with the same polychemotherapy regimen (Arm B) until tumor progression or limiting toxicity. The primary endpoint was OS, secondary endpoints included progression-free survival (PFS), response rate (ORR), safety/toxicity and quality of life.

Results

Between November 2014 and April 2019, 217 patients were registered and 165 patients were randomized following 12 weeks of induction therapy. Recruitment was stopped prematurely due to delayed accrual and emerging new therapeutical options. Oxaliplatin-fluoropyrimidine doublet and triplet regimens were the preferred induction regimens (FLO/FOLFOX 47.0%; FLOT 44.7%). Median OS from randomization for patients in Arm A was 13.3 months (95% CI 10.6-15.5) versus 11.4 months (95% CI 9.0-16.5) in Arm B (Hazard Ratio (HR) 1.02 [95% CI 0.70-1.49], p=0.91). Median PFS in Arm A and B was 4.8 months (95% CI 4.0-6.6) and 5.9 months (95% CI 3.8-9.0) respectively (HR 0.93 [95% CI 0.65-1.34], p=0.70). During maintenance phase treatment-related grade 3-5 toxicity was observed in 24.5% (Arm A) versus 27.3% (Arm B), treatment-related peripheral sensory neuropathy (grade 1,2,3) was observed in 11.8%/7.3%/2.7% (Arm A) vs. 7.3%/30.9%/9.1% (Arm B).

Conclusions

S-1 as maintenance therapy showed comparable activity in comparison to a prolonged platinum-based therapy with a favorable toxicity pattern. Updated results will be presented at the meeting.

Clinical trial identification

NCT02128243.

Legal entity responsible for the study

AIO Studien gGmbH Berlin, Germany.

Funding

Taiho Pharmaceuticals, Nordic Pharma.

Disclosure

G.M. Haag: Advisory/Consultancy, Travel/Accommodation/Expenses: Bristol-Myers Sqiobbq; Advisory/Consultancy, Research grant/Funding (institution): MSD Sharp&Dohme; Advisory/Consultancy: EsoCap; Honoraria (self): Servier; Travel/Accommodation/Expenses: Eli Lilly; Research grant/Funding (institution): Taiho; Research grant/Funding (institution): Nordic Pharma. M. Venerito: Honoraria (self): Nordic Pharma; Honoraria (self): Merck Serono; Honoraria (self): Bayer; Honoraria (self): Lilly; Honoraria (self): Sirtex; Advisory/Consultancy: Ipsen; Advisory/Consultancy: Lilly; Advisory/Consultancy: Nordic Pharma; Advisory/Consultancy: BMS; Advisory/Consultancy: MSD; Advisory/Consultancy: Eisai; Advisory/Consultancy: Amgen. B. Chibaudel: Honoraria (self): Sanofi; Honoraria (self): Roche; Honoraria (self): Pfizer; Honoraria (self): Beigene; Honoraria (self): Lilly; Honoraria (self): Servier; Honoraria (self): Bayer. F. Lordick: Honoraria (self): Amgen; Honoraria (self): Astra Zeneca; Honoraria (self): Astellas; Honoraria (self): Biontech; Honoraria (self): BMS; Honoraria (self): Eli Lilly; Honoraria (self): Elsevier; Honoraria (self): Imedex; Honoraria (self): Infomedica; Honoraria (self): Iomedico; Honoraria (self): MedScape; Honoraria (self): MedUpdate; Honoraria (self): Merck Serono; Honoraria (self): MSD; Honoraria (self): Oncovis; Honoraria (self): Promedicis; Honoraria (self): Roche; Honoraria (self): Springer Nature; Honoraria (self): StreamedUp!; Honoraria (self): Zymeworks; Non-remunerated activity/ies: EORTC Gastrointestinal Tract Cancer Group; Non-remunerated activity/ies: International Gastric Cancer Association; Non-remunerated activity/ies: ESMO. All other authors have declared no conflicts of interest.