Disclosures: All authors have declared no conflicts of interest.

Funding: Has not received any funding.

Legal entity responsible for the study: Gastric and gastroesophageal junction adenocarcinoma (GA/GEJA) patients and showed a 30% overall survival rate (5yOS) for each cStage was calculated using the Kaplan-Meier method. Patients who received preoperative chemotherapy were excluded. The proportion of MONO patients per minimally clinically important difference (MCID) category (deterioration, no change, improvement) was evaluated at EOT; in FAST, time to HRQoL deterioration (TTD) based on MCID thresholds was assessed using Kaplan-Meier estimates and Cox models.

Results: Patients in MONO (n = 40) had stable scores in all STO22 domains but deteriorated in C30 functional (role, cognitive and physical) and symptom scales (fatigue, insomnia, pain, nausea/vomiting and appetite loss). MONO treatment responders (n = 9) showed less deterioration in C30 scales. Most patients stayed stable or had clinically meaningful improvement in HRQoL. In FAST (EOX n = 74, IMAB362+EOX n = 68), a significant difference in change from baseline was only seen for the nausea/vomiting symptom scale (P<.01) favoring EOX. IMAB362+EOX delayed TTD for global health status, trouble belching, eating restrictions, feeling tense, pain interference, acid indigestion/burning, shortness of breath and HRQoL vs EOX (all P<.05).

Patients remaining on IMAB362 alone post EOX EOT generally showed better HRQoL and physical functioning than EOX alone.

Conclusion: For patients with advanced CLDN18.2 expressing GA/GEJA, IMAB362 maintained HRQoL and delayed TTD in both monotherapy and combination chemotherapy settings.

Clinical trial identification: NCT01197885 and NCT01630083.

Legal entity responsible for the study: Astellas Pharma, Inc.

Disclosure: R. Morlock: Employee: Astellas; Personal fees: Abbot Medical Optics, Ironwood, Genetech. M.R. Krukas-Hampel: Employee: IQVIA, contracted to do this analysis by Astellas. O. Tureci: Stock option owner, ex-shareholder, co-founder, CEO: Ganymed AG; Consultancy fee: Astellas; Several patent families are pending, issued, or licensed. Those relevant to this work have been acquired by Astellas.

Background: The single-arm MONO trial (NCT01197885) assessed IMAB362 (600 mg/m2) monotherapy as salvage therapy in GA/GEJA patients and showed a 30% disease control rate. The FAST trial (NCT01630083) assessed IMAB362 (loading dose 800 mg/m2 then 600 mg/m2) combination therapy as 1st line therapy (IMAB362+EOX followed by single agent IMAB362 maintenance until disease progression [DP]) vs EOX alone in GA/GEJA patients. IMAB362+EOX significantly prolonged progression-free and overall survival. We describe the MONO and FAST PRO results.

Methods: EORTC QLQ-C30 and STO22 were collected at baseline, end of IMAB362 treatment (EOT), and every 8 wks post-EOT in MONO; and at baseline, Cycle 5, EOX EOT, and post-EOT every 12 wks until DP in FAST. Both studies used mixed model repeated measures (MMRM) assuming missing at random to assess HRQoL changes from baseline. The proportion of MONO patients per minimally clinically important difference (MCID) category (deterioration, no change, improvement) was evaluated at EOT; in FAST, time to HRQoL deterioration (TTD) based on MCID thresholds was assessed using Kaplan-Meier estimates and Cox models.

RESULTS: In MONO (n = 40) had stable scores in all STO22 domains but deteriorated in C30 functional (role, cognitive and physical) and symptom scales (fatigue, insomnia, pain, nausea/vomiting and appetite loss). MONO treatment responders (n = 9) showed less deterioration in C30 scales. Most patients stayed stable or had clinically meaningful improvement in HRQoL. In FAST (EOX n = 74, IMAB362+EOX n = 68), a significant difference in change from baseline was only seen for the nausea/vomiting symptom scale (P < 0.01) favoring EOX. IMAB362+EOX delayed TTD for global health status, trouble belching, eating restrictions, feeling tense, pain interference, acid indigestion/burning, shortness of breath and HRQoL vs EOX (all P < 0.05).

Patients remaining on IMAB362 alone post EOX EOT generally showed better HRQoL and physical functioning than EOX alone.

CONCLUSION: For patients with advanced CLDN18.2 expressing GA/GEJA, IMAB362 maintained HRQoL and delayed TTD in both monotherapy and combination chemotherapy settings.

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