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Zanidatamab + Chemotherapy for First-Line Treatment of Human Epidermal Growth Factor Receptor 2-Positive Advanced or Metastatic Gastro-Oesophageal Adenocarcinoma: New and Updated Data From a Phase 2 Trial

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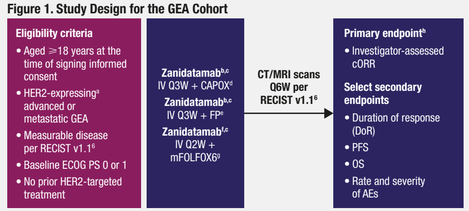
Background

- Approximately 20% of patients with gastro-oesophageal adenocarcinomas (GEAs) have tumours with human epidermal growth factor receptor 2 (HER2) overexpression/amplification[1]
- However, HER2-targeted treatment options for the first-line treatment of patients with metastatic HER2-positive GEA are limited[2]
- Zanidatamab is a humanised, IgG1-like, dual HER2-targeted bispecific antibody that binds to 2 distinct domains on HER2 in a *trans* orientation, promoting HER2 receptor crosslinking and driving multiple mechanisms of action, including[3]:
  - Immune-mediated effects: complement-dependent cytotoxicity, antibody dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis
  - Prevention of HER2 hetero- and homo-dimerisation and intracellular signalling
  - Facilitation of HER2 internalisation and subsequent degradation
- In a previous analysis of this ongoing phase 2 trial, zanidatamab + chemotherapy demonstrated encouraging efficacy (confirmed objective response rate [cORR] of 79% and median progression-free survival [PFS] of 12.5 months) as a first-line treatment for patients with HER2-positive advanced or metastatic GEA (mGEA) with a manageable safety profile[4]
  - After a median follow-up of 26.5 months, median overall survival (OS) was not yet reached
- Here, we report new and updated results, including OS data

Methods

- This phase 2 trial (NCT03929666) is a multicentre, global, open-label, 2-part study of zanidatamab + standard combination chemotherapy for patients with selected unresectable, locally advanced, recurrent or metastatic HER2-expressing gastrointestinal cancers, including GEA

Figure 1. Study Design for the GEA Cohort



[a]As determined by local or central assessment of HER2 status (IHC 3+ or IHC 2+ regardless of FISH status) in Part 1 and by central assessment of HER2 status (IHC 3+ or IHC 2+ and FISH+) in Part 2; [b]Zanidatamab 30 mg/kg, 1800 mg (patients <70 kg) or 2400 mg (patients ⩾70 kg); [c]Per protocol, chemotherapy was required for 6 cycles except for intolerability or disease progression then could be continued, attenuated (5-FU or capecitabine could be maintained if oxaliplatin was discontinued due to toxicity; however, if 5-FU or capecitabine was discontinued, oxaliplatin should have been discontinued) or discontinued per the investigator's and patient's discretion. Patients who discontinued chemotherapy due to reasons not related to zanidatamab toxicity without disease progression could continue treatment with zanidatamab monotherapy; [d]CAPOX consisted of capecitabine 1000 mg/m² PO BID on days 1–14 Q3W + oxaliplatin 130 mg/m² IV Q3W; [e]FP consisted of cisplatin 80 mg/m² IV Q3W + 5-FU 800 mg/m²/day IV on days 1–5 Q3W; [f]Zanidatamab 20 mg/kg, 1200 mg (patients <70 kg) or 1600 mg (patients ⩾70 kg) IV Q2W; [g]mFOLFOX6 consisted of leucovorin 400 mg/m² IV Q2W + oxaliplatin 85 mg/m² IV Q2W + 5-FU 1200 mg/m²/day continuous IV infusion for 48 hours Q2W; [h]Part 2 evaluated the antitumour activity of zanidatamab based on the primary endpoint of objective response rate per investigator assessment.
AE, adverse event; BID, twice a day; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; MRI, magnetic resonance imaging; PO, by mouth; Q2W, every 2 weeks; Q3W, every 3 weeks; Q6W, every 6 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1.

- For patients with advanced HER2-expressing GEA (**Figure 1**):
  - Part 1 assessed safety and established the recommended dosing of zanidatamab in combination with 3 multi-agent chemotherapy regimens (CAPOX: capecitabine plus oxaliplatin; FP: 5-fluorouracil [5-FU] plus cisplatin; and modified FOLFOX6 [mFOLFOX6]: 5-FU/leucovorin plus oxaliplatin)[5]
    - Eligibility was based on the local or central assessment of HER2 status (immunohistochemistry [IHC] 3+ or 2+ with or without gene amplification)
  - Part 2 assessed the antitumour activity of zanidatamab + chemotherapy at doses established in Part 1
    - Eligibility was based on the central assessment of HER2 status (centrally confirmed HER2-positive: IHC 3+ or IHC 2+ and fluorescence in situ hybridisation [FISH]+)
- Eligible patients were treated with zanidatamab + physician's choice of combination chemotherapy regimens (⩾6 cycles), with mandatory prophylaxis (acetaminophen, diphenhydramine and corticosteroid) for potential infusion-related reactions (IRRs)
- After the first 25 patients were enrolled, mandatory antidiarrhoeal prophylaxis (loperamide 4 mg twice daily starting on the first day of treatment and continuing for ⩾7 days) was added to cycle 1
- Efficacy analyses reported here include patients from Part 1 and Part 2 with centrally confirmed HER2-positive GEA, and safety analyses include all patients

Results

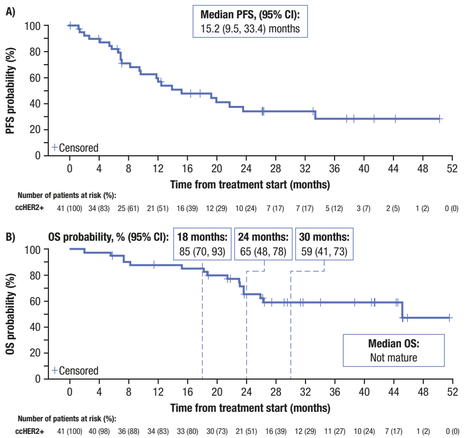
Table 1. Demographics and Baseline Characteristics in Patients With HER2-Expressing mGEA (All Patients)

	Total (N=46)
Age, median, years (range)	58 (26-82)
Male, n (%)	39 (85)
Race,[a] n (%)	
White	28 (61)
Asian	17 (37)
Unknown	1 (2)
Ethnicity, n (%)	
Hispanic or Latino	3 (7)
Not Hispanic or Latino	43 (93)
ECOG PS, n (%)	
0	26 (57)
1	20 (43)
Disease subtype, n (%)	
Gastric	19 (41)
Gastro-oesophageal junction	16 (35)
Oesophageal	11 (24)
Disease stage at initial diagnosis, n (%)	
IB	2 (4)
II	2 (4)
III	4 (9)
IV	38 (83)
Centrally confirmed HER2-positive,[b] n (%)	41 (89)
IHC 3+	36 (78)[c]
IHC 2+/FISH+	5 (11)

[a]Patients could have reported >1 race category; [b]Centrally confirmed HER2-positive was defined as IHC 3+ or IHC 2+ with FISH+ by central assessment; [c]Included 35 patients with IHC 3+/FISH+ tumours and 1 patient having IHC 3+ tumours with no FISH data.
ECOG PS, Eastern Cooperative Oncology Group performance status.

- Between Aug. 2019 and Feb. 2022, 46 patients with metastatic HER2-expressing GEA received zanidatamab in combination with chemotherapy (CAPOX, n=20; FP, n=2; mFOLFOX6, n=24)
- As of 17 Jan. 2024, the median (range) duration of follow-up was 41.5 (23.0-52.7) months
  - Treatment was ongoing for 10 (22%) patients and 14 (30%) patients were in active post-treatment follow-up
- Overall, 41 (89%) patients had tumours that were centrally confirmed as HER2-positive (**Table 1**)
  - Of these patients, 37 had ⩾1 post-baseline response assessment and were included in the response-evaluable analysis set

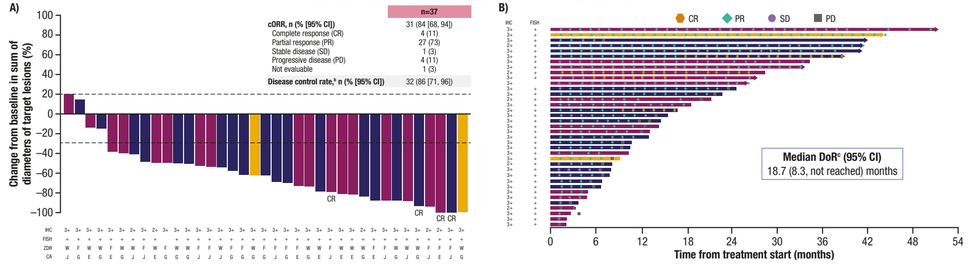
Figure 3. Kaplan-Meier Plot of PFS (A) and OS (B) in Patients With Centrally Confirmed HER2-Positive mGEA



ccHER2+, centrally confirmed human epidermal growth factor receptor 2-positive.

- The median PFS increased from the previous analysis[4] to 15.2 (95% CI: 9.5, 33.4) months (**Figure 3A**); the longest PFS was 50.4 months, which was reported in a patient who received zanidatamab + mFOLFOX6 treatment that was ongoing at time of data cut-off

Figure 2. Disease Response (A) and Treatment Duration and Response (B) in Patients With Centrally Confirmed HER2-Positive mGEA (Response-Evaluable Analysis Set[a])



Arrows indicate that treatment is ongoing.
[a]Patients who underwent ⩾1 post-baseline response assessment per RECIST v1.1[6] or discontinued treatment due to clinical progression or death were considered response evaluable; [b]Disease control was defined as a best overall response of stable disease or confirmed complete response or partial response. [c]Duration of response was assessed in the 31 patients with a confirmed complete response or partial response; [d]Treatment was ongoing at time of data cut-off in 1 additional patient whose tumours were not centrally confirmed HER2-positive.
CA, primary diagnosis; E, oesophageal adenocarcinoma; F, flat dose; G, gastric adenocarcinoma; J, gastro-oesophageal junction adenocarcinoma; Q2W, every 2 weeks; Q3W, every 3 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1; W, weight-based dose; ZDR, zanidatamab dose regimen.

- With additional follow-up, the cORR increased to 84% (n/N=31/37 [95% confidence interval [CI]: 68, 94]) from 79% (n/N=30/38 [95% CI: 63, 90]) in the previous analysis[4]
  - One additional patient achieved a complete response (n=4; 11%) (**Figure 2**)

Table 2. Summary of Safety Outcomes in Patients With HER2-Expressing mGEA (All Patients)

	Zanidatamab + CAPOX (n=20)		Zanidatamab + mFOLFOX6 (n=24)		Zanidatamab + FP (n=2)		Total (N=46)	
Any-grade TRAE,[a] n (%)	20 (100)		24 (100)		2 (100)		46 (100)	
Grades 1-2	10 (50)		6 (25)		1 (50)		17 (37)	
Grades 3-4	10 (50)		18 (75)		1 (50)		29 (63)	
Grade 5	0 (0)		0 (0)		0 (0)		0 (0)	
Serious TRAE,[a] n (%)	2 (10)		5 (21)		1 (50)		8 (17)	
TRAEs leading to zanidatamab discontinuation, n (%)	0 (0)		2 (8)		0 (0)		2 (4)[c]	
	All grades	**Grade ⩾3**	**All grades**	**Grade ⩾3**	**All grades**	**Grade ⩾3**	**All grades**	**Grade ⩾3**
Most common TRAEs,[a,b] n (%)								
Diarrhoea[d]	18 (90)	6 (30)	23 (96)	9 (38)	2 (100)	1 (50)	43 (93)	16 (35)[e]
Nausea	15 (75)	1 (5)	21 (88)	2 (8)	1 (50)	0 (0)	37 (80)	3 (7)
Peripheral neuropathy	14 (70)	0 (0)	16 (67)	0 (0)	0 (0)	0 (0)	30 (65)	0 (0)
Fatigue	7 (35)	0 (0)	16 (67)	2 (8)	0 (0)	0 (0)	23 (50)	2 (4)
Decreased appetite	7 (35)	0 (0)	13 (54)	0 (0)	1 (50)	0 (0)	21 (46)	0 (0)
Vomiting	4 (20)	1 (5)	12 (50)	2 (8)	0 (0)	0 (0)	16 (35)	3 (7)
Hypokalaemia	3 (15)	2 (10)	11 (46)	8 (33)	0 (0)	0 (0)	14 (30)	10 (22)
Stomatitis	3 (15)	0 (0)	10 (42)	0 (0)	0 (0)	0 (0)	13 (28)	0 (0)
Anaemia	1 (5)	0 (0)	9 (38)	0 (0)	0 (0)	0 (0)	10 (22)	0 (0)
Dysgeusia	5 (25)	0 (0)	5 (21)	0 (0)	0 (0)	0 (0)	10 (22)	0 (0)
IRR	6 (30)	0 (0)	3 (12)	0 (0)	1 (50)	0 (0)	10 (22)	0 (0)
Decreased neutrophil count	3 (15)	0 (0)	7 (29)	2 (8)	0 (0)	0 (0)	10 (22)	2 (4)
PPE	8 (40)	1 (5)	2 (8)	0 (0)	0 (0)	0 (0)	10 (22)	1 (2)
Hypomagnesaemia	3 (15)	0 (0)	6 (25)	1 (4)	0 (0)	0 (0)	9 (20)	1 (2)
Decreased white blood cell count	0 (0)	0 (0)	7 (29)	2 (8)	0 (0)	0 (0)	7 (15)	2 (4)
Acute kidney injury	0 (0)	0 (0)	2 (8)	1 (4)	1 (50)	1 (50)	3 (7)	2 (4)
Treatment-related AESI occurring in any patient, n (%)								
IRR	6 (30)	0 (0)	3 (12)	0 (0)	1 (50)	0 (0)	10 (22)	0 (0)
Ejection fraction decreased	0 (0)	0 (0)	2 (8)	0 (0)	0 (0)	0 (0)	2 (4)	0 (0)
Pneumonitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

[a]TRAEs could be related to zanidatamab and/or chemotherapy; [b]Any-grade TRAEs occurred in >20% of all patients or grade >3 TRAEs in >2 patients in the total population; [c]Both patients discontinued zanidatamab treatment due to treatment-related diarrhoea; [d]13 of 25 patients (52%) had grade >3 diarrhoea before the protocol amendment mandating antidiarrhoeal prophylaxis; 3 out of 21 patients (14%) had grade >3 diarrhoea after receiving antidiarrhoeal prophylaxis. [e]1 patient had grade 5 diarrhoea.
AESI, adverse event of special interest; PPE, Palmar-plantar erythrodysaesthesia syndrome.

- All 46 patients with HER2-expressing metastatic GEA experienced ⩾1 treatment-related adverse event (TRAE), deemed related to zanidatamab and/or chemotherapy
- Grade ⩾3 TRAEs occurred in 29 (63%) patients (**Table 2**), similar to the previous analysis (n=28; 61%)[4]
- Diarrhoea remained the most common grade ⩾3 TRAE (n=16; 35%)[4]
  - At time of data cut-off, grade ⩾3 diarrhoea events were resolved in 9 patients, and remained ongoing but were mitigated to grade 1 or 2 in 7 patients
  - The incidence of grade ⩾3 diarrhoea was lower after antidiarrhoeal prophylaxis was implemented
    - Treatment-related grade ⩾3 diarrhoea occurred in 3 out of 21 patients (14%) for whom antidiarrhoeal prophylaxis was mandated compared with 13 out of 25 patients (52%) without antidiarrhoeal prophylaxis
  - Treatment-related grade ⩾3 diarrhoea predominantly occurred during Cycle 1; the median duration was 3 (interquartile range: 2-5) days, irrespective of the cycle in which the adverse event occurred
- Treatment-related IRRs occurred in 10 patients (22%), and all events were grades 1-2
- Serious TRAEs occurred in 8 (17%) patients; no new patients reported a serious TRAE since the previous analysis[4]
- There were no treatment-related deaths

Conclusions

- With approximately 3.5 years of median follow-up, first-line treatment with zanidatamab + standard chemotherapy continues to show promising and antitumour activity in patients with HER2-positive metastatic GEA
  - The cORR was 84% with 4 complete responses
  - The median DoR was 18.7 months
  - The median PFS was 15.2 months
  - Kaplan-Meier–estimated 30-month OS was 59%
- The safety and tolerability profile of zanidatamab + chemotherapy remained manageable with no new safety signals identified[4]
  - The incidence of grade ⩾3 diarrhoea was <15% for patients treated after the implementation of mandated antidiarrhoeal prophylaxis
  - Treatment discontinuation due to TRAEs were infrequent, and there were no treatment-related deaths
- The clinical development of zanidatamab in HER2-positive GEA is ongoing
  - The global, randomised, phase 3 trial of HERIZON-GEA-01 (NCT05152147) is currently enrolling patients to assess the efficacy and safety of zanidatamab plus chemotherapy with or without tislelizumab, a PD-1 inhibitor, in the first-line setting for patients with HER2-positive advanced or metastatic GEA

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