Phase Ib/II Open-Label, Randomized Evaluation of 2L Atezolizumab (atezo) + BL-8040 vs Control in MORPHEUS-Pancreatic Ductal Adenocarcinoma (M-PDAC) and MORPHEUS-Gastric Cancer (M-GC)

Abstract # 712
Poster # L1

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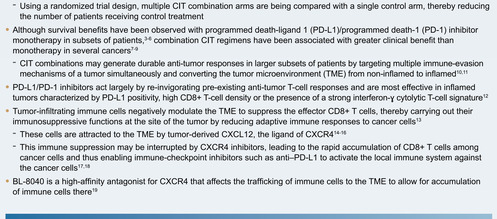
MORPHEUS PLATFORM AND COMBINATION THERAPY

- The MORPHEUS platform consists of multiple global, open-label, randomized umbrella Phase Ib/II trials designed to accelerate the development of cancer immunotherapy (CIT) combinations in several indications by identifying early signals and establishing proof-of-concept clinical data[1,2]
  - Using a randomized trial design, multiple CIT combination arms are being compared with a single control arm, thereby reducing the number of patients receiving control treatment
- Although survival benefits have been observed with programmed death-ligand 1 (PD-L1)/programmed death-1 (PD-1) inhibitor monotherapy in subsets of patients,[3-6] combination CIT regimens have been associated with greater clinical benefit than monotherapy in several cancers[7-9]
  - CIT combinations may generate durable anti-tumor responses in larger subsets of patients by targeting multiple immune-evasion mechanisms of a tumor simultaneously and converting the tumor microenvironment (TME) from non-inflamed to inflamed[10,11]
- PD-L1/PD-1 inhibitors act largely by re-invigorating pre-existing anti-tumor T-cell responses and are most effective in inflamed tumors characterized by PD-L1 positivity, high CD8+ T-cell density or the presence of a strong interferon-γ cytolytic T-cell signature[12]
- Tumor-infiltrating immune cells negatively modulate the TME to suppress the effector CD8+ T cells, thereby carrying out their immunosuppressive functions at the site of the tumor by reducing adaptive immune responses to cancer cells[13]
  - These cells are attracted to the TME by tumor-derived CXCL12, the ligand of CXCR4[14-16]
  - This immune suppression may be interrupted by CXCR4 inhibitors, leading to the rapid accumulation of CD8+ T cells among cancer cells and thus enabling immune-checkpoint inhibitors such as anti–PD-L1 to activate the local immune system against the cancer cells[17,18]
- BL-8040 is a high-affinity antagonist for CXCR4 that affects the trafficking of immune cells to the TME to allow for accumulation of immune cells there[19]

RATIONALE FOR CIT COMBINATION AND STUDY DESIGN

- Because a CXCR4 antagonist, which alters the immunosuppressive TME, may enable an immune-checkpoint inhibitor to more effectively activate the local immune system against cancer cells, BL-8040 was tested in combination with atezolizumab (anti–PD-L1) in patients with advanced/metastatic pancreatic ductal adenocarcinoma (PDAC) (Figure 1A) and gastric cancer (GC) (Figure 1B) in MORPHEUS-PDAC (NCT03193190) and MORPHEUS-GC (NCT03281369), respectively

Figure 1. Study Design of (A) MORPHEUS-PDAC and (B) MORPHEUS-GC



FU, fluorouracil; mFOLFOX6, 5-fluorouracil, leucovorin, and oxaliplatin; PD, progressive disease; PDAC, pancreatic ductal adenocarcinoma; R, randomization. Stage 2 is planned only for MORPHEUS-PDAC.

- The primary endpoint of both studies was:
  - Investigator-assessed objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1)
- Key secondary endpoints presented here included:
  - Investigator-assessed progression-free survival (PFS) and disease control rate (DCR) per RECIST 1.1
  - Overall survival (OS)
  - Percentage of patients alive at 6 months in MORPHEUS-PDAC
  - Investigator-assessed duration of response (DOR) per RECIST 1.1 in MORPHEUS-GC
  - Percentage of participants with adverse events (AEs)
  - Pharmacokinetics (PK) and percentage of patients with anti-drug antibodies (ADAs) to atezolizumab in MORPHEUS-PDAC
- Exploratory biomarker analyses were also conducted
- Key exclusion criteria for both studies included symptomatic, untreated or actively progressing central nervous system metastases; active or history of autoimmune disease or immune deficiency; and a history of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis

MORPHEUS-PDAC (NCT03193190): 18-WEEK INTERIM ANALYSIS AND UPDATED OS ANALYSIS

Standard of Care for Patients With PDAC

- Combination chemotherapy regimens are the standard of care for PDAC, but the prognosis for patients with metastatic disease remains poor[20,21]
- There is a strong unmet need for improved medical treatment for patients with PDAC

Inclusion Criteria and Treatment

- MORPHEUS-PDAC is a global, open-label, randomized, Phase Ib/II trial of atezolizumab plus BL-8040 compared with chemotherapy that was conducted in 2 stages in patients with PDAC[2]
- Key inclusion criteria were a histologically or cytologically confirmed diagnosis of metastatic PDAC and disease progression ≤ 6 months after treatment with 1 line of 5-fluorouracil (FU)– or gemcitabine-based chemotherapy in the metastatic setting; ≥ 18 years of age; Eastern Cooperative Oncology Group performance status (ECOG PS) score 0-1 and measurable disease by RECIST 1.1
- Eligible patients had to provide an entry biopsy before being randomized to receive either atezolizumab 1200 mg intravenously (IV) every 3 weeks plus BL-8040 (1.25 mg/kg subcutaneously [SC] on days 1-5, then 1.25 mg/kg SC 3 times a week), or chemotherapy control (gemcitabine plus nab-paclitaxel or 5-fluorouracil, leucovorin, and oxaliplatin [mFOLFOX6]) in stage 1 of the trial (Figure 1A)
- Patients in stage 1 who experienced disease progression per RECIST 1.1, unacceptable toxicity or loss of clinical benefit as determined by the investigator could receive a different treatment combination during stage 2 if they met the eligibility criteria (Figure 1A)

Patient demographics and disposition

- Fifteen patients were randomized to each of the atezolizumab plus BL-8040 and chemotherapy control arms, respectively
- An interim analysis of efficacy and safety was conducted at the 18-week cutoff on September 7, 2018
- An updated analysis of OS was conducted on July 9, 2019
- The patient baseline characteristics and demographics are presented in Table 1

Table 1. Baseline Demographics and Disease Characteristics in MORPHEUS-PDAC

Variable, n (%)	Atezolizumab + BL-8040 (n = 15)	Chemotherapy (n = 15)
Age ≥ 65 years	8 (53.3)	7 (46.7)
Male	10 (66.7)	4 (26.7)
Baseline ECOG PS 1	7 (46.7)	9 (60.0)
Prior chemotherapy		
5-FU	9 (60.0)	6 (40.0)
Gemcitabine	6 (40.0)	9 (60.0)
Baseline albumin level ≥ 3.5 g/dL	13 (86.7)	8 (53.3)
Baseline CRP level > 1.2 mg/dL	2 (13.3)	2 (13.3)
Baseline LDH level		
≥ 1.5 × ULN and < 2.5 × ULN	1 (6.7)	0
≥ 2.5 × ULN	0	1 (6.7)
Baseline NLR ≥ 5	3 (20.0)	6 (40.0)
Metastatic sites at enrollment, n		
1	10 (66.7)	4 (26.7)
2	1 (6.7)	6 (40.0)
3	4 (26.7)	2 (13.3)
≥ 4	0	3 (20.0)

CRP, C-reactive protein; ECOG PS, Eastern Cooperative Oncology Group performance status; LDH, lactate dehydrogenase; NLR, neutrophil-to-lymphocyte ratio.

Efficacy

- The efficacy data are summarized in Table 2 and in the additional data (see QR code)

Table 2. Efficacy in MORPHEUS-PDAC

Variable, n (%)	Atezolizumab + BL-8040 (n = 14)[a]	Chemotherapy (n = 15)
Confirmed investigator-assessed ORR per RECIST 1.1, n (%) [95% CI][b,c]	0 [0.00, 23.6]	0 [0.00, 21.8]
CR	0 [0.00, 23.6]	0 [0.00, 21.8]
PR	0 [0.00, 23.6]	0 [0.00, 21.8]
SD, n (%) [95% CI]	1 (7.1) [0.18, 33.87]	6 (40.0) [16.34, 67.71]
PD, n (%) [95% CI]	12 (85.7) [57.19, 98.22]	5 (33.3) [11.82, 61.62]
PFS (18-week cutoff)[c]		
Progression event or death, n (%)	14 (100)	12 (80)
Median PFS, mo (95% CI)	1.64 (1.41, 1.87)	2.51 (1.41, 4.50)
Updated OS[d]		
Deaths, n (%)	14 (100)	14 (93.3)
Median time to death, mo (95% CI)	5.19 (3.25, 8.87)	6.78 (2.27, 9.66)
Range, mo	2.0-16.4	0.3^-15.3
HR (95% CI)	0.99 (0.46, 2.13)	
Patients alive at 6 mo: event-free rate, % (95% CI)	42.86 (16.93, 68.78)	64.29 (39.19, 89.39)

CR, complete response; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease.
[a] One patient only received BL-8040 priming and did not receive atezolizumab, and was therefore not evaluable for efficacy.
[b] Data were missing from 1 patient in the atezolizumab plus BL-8040 arm and 4 patients from the chemotherapy arm.
[c] Clinical cutoff date, September 7, 2018.
[d] Clinical cutoff date, July 9, 2019.
^ Censored.

Safety

- The safety data from MORPHEUS-PDAC are summarized in Table 3
- AEs that led to discontinuation of any treatment in the chemotherapy arm were Grade 3 deep vein thrombosis in 1 patient (6.7%) and Grade 5 disseminated intravascular coagulation in 1 patient (6.7%). No AEs led to drug discontinuation in the atezolizumab plus BL-8040 arm
- AEs that led to any drug dose modification or interruption were:
  - Atezolizumab plus BL-8040 arm: fatigue, nausea ascites, dehydration, hypokalemia, acute cholangitis and embolism (each in 1 patient [6.7%])
  - Chemotherapy arm: neutropenia (3 patients [20%]), decreased white blood cell count (2 patients [13.3%]) and asthenia, duodenal obstruction, mechanical ileus, thrombocytopenia, anemia, neutrophil count decreased and atrial fibrillation (each in 1 patient [6.7%])

Table 3. Safety Summary[a]

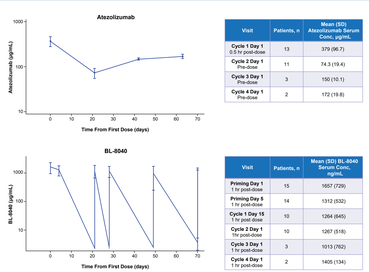
n (%)	Atezolizumab + BL-8040 (n = 15)	Chemotherapy (n = 15)
Deaths[b]	10 (66.7)	6 (40.0)
Patients with ≥ 1 AE	15 (100)	15 (100)
Related AE	15 (100)	13 (86.7)
SAE	4 (26.7)	7 (46.7)
Related SAE	1 (6.7)	3 (20.0)
Grade 3-5 AE	7 (46.7)	10 (66.7)
Grade 5 AE	0	1 (6.7)
Related AE leading to dose modification/interruption[c]	5 (33.3)	12 (80.0)
Related AE leading to withdrawal from treatment[c]	0	1 (6.7)

AE, adverse event; SAE, serious adverse event.
[a] Clinical cutoff date, September 7, 2018.
[b] Death from any cause.
[c] AE leading to withdrawal from treatment/dose modification/interruption of any drug.

PK and PD

- The PK of atezolizumab and BL-8040 are summarized in Figure 2
  - Mild atezolizumab accumulation in C_{trough} was observed throughout the treatment period
  - Serum trough levels of atezolizumab were maintained above the target of 6 µg/mL for maximum receptor occupancy in all patients
- The expected long receptor occupancy of BL-8040 is predicted to lead to sustained PD effects, likely associated with C_{max}
- ADAs for atezolizumab were observed in 1 of 9 patients who reached Cycle 2 Day 1 (approximately 11.1% incidence)
- ADAs were not evaluated with BL-8040

Figure 2. PK of (A) atezolizumab and (B) BL-8040 in patients in MORPHEUS-PDAC



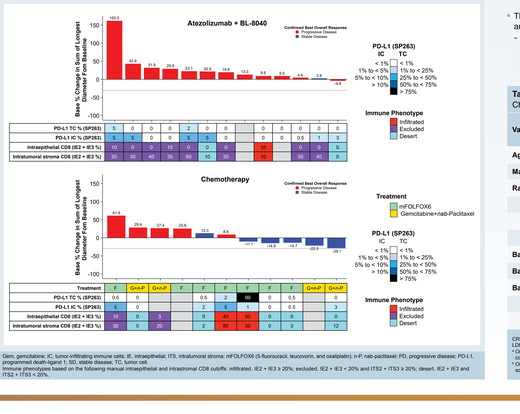
Visit	Patients, n	Mean (SD) Atezolizumab Serum Conc, µg/mL
Cycle 1 Day 1 0.5 hr post-dose	13	379 (66.7)
Cycle 1 Day 1 Pre-dose	11	74.3 (19.4)
Cycle 3 Day 1 Pre-dose	3	150 (10.1)
Cycle 4 Day 1 Pre-dose	2	172 (19.8)

Visit	Patients, n	Mean (SD) BL-8040 Serum Conc, ng/mL
Priming Day 1 1 hr post-dose	15	1657 (729)
Priming Day 5 1 hr post-dose	14	1312 (532)
Cycle 1 Day 15 1 hr post dose	10	1264 (645)
Cycle 2 Day 1 1 hr post-dose	10	1267 (518)
Cycle 3 Day 1 1 hr post-dose	3	1013 (762)
Cycle 4 Day 1 1 hr post-dose	2	1405 (134)

Biomarker analysis

- Biomarker data are summarized according to patient response in Figure 3

Figure 3. Biomarker Analyses of Baseline Tumor Samples vs Patient Response



Gem, gemcitabine; IC, tumor-infiltrating immune cells; IE, intraepithelial; ITS, intratumoral stroma; mFOLFOX6 (5-fluorouracil, leucovorin, and oxaliplatin); n-P, nab-paclitaxel; PD, progressive disease; PD-L1, programmed death-ligand 1; SD, stable disease; TC, tumor cell.
Immune phenotypes based on the following manual intraepithelial and intratumoral CD8 cutoffs: infiltrated, IE2 + IE3 ≥ 20%, excluded, IE2 + IE3 < 20% and ITS2 + ITS3 ≥ 20%; desert, IE2 + IE3 and ITS2 + ITS3 < 20%.

MORPHEUS-GC (NCT03281369): 24-WEEK INTERIM ANALYSIS

Standard of care for patients with GC

- Combination chemotherapy regimens are the first-line standard of care for metastatic GC[22] and are complemented with trastuzumab for the treatment of human epidermal growth factor receptor 2 (HER2)–overexpressing GC[23]
- A variety of single agents, including docetaxel, paclitaxel, irinotecan and ramucirumab, are used as second-line treatment, as is the combination of ramucirumab with paclitaxel[22]
- Effective new treatments for gastric cancer are urgently needed

Eligibility and treatment

- MORPHEUS-GC is a global, open-label, randomized, Phase Ib/II trial of atezolizumab plus BL-8040 compared with paclitaxel plus ramucirumab in patients with GC[2]
- Key inclusion criteria were a histologically or cytologically confirmed diagnosis of locally advanced, unresectable or metastatic gastric adenocarcinoma or carcinoma of the gastroesophageal junction that had progressed during or following a first-line platinum- or fluoropyrimidine-containing chemotherapy regimen; age ≥ 18 years; ECOG PS score 0–1 and measurable disease per RECIST 1.1
- Eligible patients had to provide an entry biopsy before being randomized to receive either atezolizumab 1200 mg IV every 3 weeks plus BL-8040 (1.25 mg/kg subcutaneously [SC] on days 1-5, then 1.25 mg/kg SC 3 times a week), or control treatment (paclitaxel plus ramucirumab) (Figure 1B) until they experienced unacceptable toxicity and/or loss of clinical benefit as determined by the investigator in the experimental arm, or PD per RECIST 1.1 in the control arm

Patient demographics and disposition

- Fifteen patients were randomized to the atezolizumab plus BL-8040 arm and 16 patients to the paclitaxel plus ramucirumab control arm
- An interim analysis of efficacy and safety was conducted at the 24-week cutoff on July 11, 2019
  - Treatment was ongoing in 6 patients (40%) in the atezolizumab plus BL-8040 arm and 9 patients (6.25%) in the control arm
- The patients' baseline characteristics and demographics are summarized in Table 4
  - The atezolizumab plus BL-8040 arm had a smaller proportion of Asian patients and fewer patients with baseline albumin levels ≥ 35 g/dL, but otherwise, the treatment arms were generally well balanced

Table 4. Baseline Demographics and Disease Characteristics in MORPHEUS-GC

Variable, n (%)	Atezolizumab + BL-8040 (n = 13)[a]	Paclitaxel + Ramucirumab (n = 12)[a]
Age ≥ 65 years	4 (30.8)	6 (50.0)
Male	11 (84.6)	9 (75.0)
Race		
Asian	5 (38.5)	7 (58.3)
White	6 (46.2)	5 (41.7)
Unknown	2 (15.4)	0
Baseline ECOG PS 1	10 (76.9)	8 (66.7)
Baseline albumin level ≥ 35 g/dL	10 (76.9)	11 (91.7)
Baseline CRP level > 12 mg/dL	2 (18.2)	4 (36.4)
< 1.5 × ULN	11 (91.7)	9 (75.0)
≥ 1.5 × ULN and < 2.5 × ULN	1 (8.3)	3 (25.0)

CRP, C-reactive protein; ECOG PS, Eastern Cooperative Oncology Group performance status; LDH, lactate dehydrogenase.
[a] One patient withdrew before the first treatment infusion due to an AE, and 1 patient withdrew consent before the first treatment; hence, 13 patients were evaluable for efficacy and safety.
[b] One patient did not meet the eligibility criteria and 3 withdrew consent before the first treatment, so 12 patients were evaluable for efficacy and safety.

Efficacy

- The efficacy data from MORPHEUS-GC are summarized in Table 5 and the additional content (see QR code)

Table 5. Efficacy in MORPHEUS-GC[a]

Variable	Atezolizumab + BL-8040 (n = 13)[b]	Paclitaxel + Ramucirumab (n = 12)[c]
Confirmed investigator-assessed ORR per RECIST 1.1, n (%) [95% CI][d]	2 (15.4) [1.92, 45.45]	2 (16.7) [2.09, 48.41]
CR	0 [0.00, 24.71]	0 [0.00, 26.46]
PR	2 (15.4) [1.92, 45.45]	2 (16.7) [2.09, 48.41]
SD, n (%) [95% CI]	1 (7.7) [0.19, 36.03]	8 (66.7) [34.89, 90.08]
PD, n (%) [95% CI]	8 (61.5) [31.58, 86.14]	2 (16.7) [2.09, 48.41]
DCR[e]	3 (23.1) [5.04, 53.81]	8 (66.7) [34.89, 90.08]
Progression event or death, n (%)	10 (76.9)	10 (83.3)
Median PFS per investigator-assessed RECIST 1.1, mo	1.92	5.75
Deaths, n (%)	6 (46.2)	6 (50.0)
Median OS, mo	5.91	8.1

CR, complete response; DCR, disease control rate; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease.
[a] Clinical cutoff date, July 11, 2019.
[b] One patient withdrew before the first treatment infusion due to an AE, and 1 patient withdrew consent before the first treatment; hence, 13 patients were evaluable for efficacy and safety.
[c] One patient did not meet the eligibility criteria and 3 withdrew consent before the first treatment, so 12 patients were evaluable for efficacy and safety.
[d] Data were missing from 2 patients in the atezolizumab plus BL-8040 arm
[e] Criteria for disease control are either response and/or SD or better for ≥ 12 weeks.

Safety

- The safety data for MORPHEUS-GC are summarized in Table 6

Table 6. Safety Summary for MORPHEUS-GC[a]

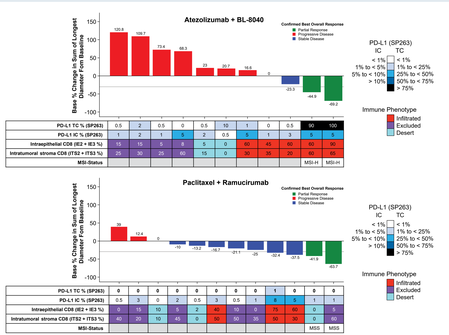
n (%)	Atezolizumab + BL-8040 (n = 13)[b]	Paclitaxel + Ramucirumab (n = 12)[c]
Deaths[d]	6 (46.2)	6 (50.0)
Patients with ≥ 1 AE	13 (100)	12 (100)
Related AE	13 (100)	12 (100)
Grade 3-4 AE	9 (69.2)	9 (75.0)
Related Grade 3-4 AE	6 (46.2)	6 (50.0)
Serious AE	4 (30.8)	6 (50.0)
Related serious AE	1 (7.7)	1 (8.3)
Grade 5 AE	0	0
AE leading to withdrawal from treatment	2 (15.4)	1 (8.3)
Related AE leading to dose modification/interruption	6 (46.2)	9 (75.0)

AE, adverse event.
[a] Clinical cutoff date, July 11, 2019.
[b] One patient withdrew before the first treatment infusion due to an AE, and 1 patient withdrew consent before the first treatment; hence, 13 patients were evaluable for efficacy and safety.
[c] One patient did not meet the eligibility criteria and 3 withdrew consent before the first treatment, so 12 patients were evaluable for efficacy and safety.
[d] Death from any cause.

Biomarker analysis

- Biomarker data are summarized in Figure 4

Figure 4. Biomarker Analyses of Baseline Tumor Samples vs Patient Response



IE, intraepithelial; ITS, intratumoral stroma; MSI-H, microsatellite instability high; MSS, microsatellite stable; PD, progressive disease; PD-L1, programmed death-ligand 1; PR, partial response; SD, stable disease; TC, tumor cell. Immune phenotypes based on the following manual intraepithelial and intratumoral CD8 cutoffs: infiltrated, IE2 + IE3 ≥ 20%, excluded, IE2 + IE3 < 20% and ITS2 + ITS3 ≥ 20%; desert, IE2 + IE3 and ITS2 + ITS3 < 20%.

CONCLUSIONS FOR MORPHEUS-PDAC AND MORPHEUS-GC

- Treatment with atezolizumab plus BL-8040 led to limited responses in patients with PDAC and GC
- No new safety signals were identified for the combination of atezolizumab plus BL-8040. The AEs observed were consistent with the known safety profiles of the individual study treatments
- Atezolizumab PK were generally comparable to historical data
- BL-8040 PK in patients with solid tumors have not been explored extensively to date, but data from MORPHEUS-PDAC suggest that the expected long receptor occupancy of BL-8040 is predicted to result in sustained PD effects
- Biomarker analyses showed that:
  - In MORPHEUS-PDAC, no associations were seen between any of the biomarkers evaluated and disease response, but the number of patients was small and most patients in the atezolizumab plus BL-8040 arm had disease progression
  - In MORPHEUS- GC, the 2 patients who had a PR had microsatellite instability–high status and an inflamed tumor phenotype and were PD-L1-positive
  - In the control arms, no association was observed between the biomarkers evaluated and responses to treatment

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ACKNOWLEDGMENTS

- The patients and their families
- The investigators and clinical study sites
- This study is sponsored by F. Hoffmann-La Roche, Ltd
- Medical writing support for this poster was provided by Samantha Santangelo, PhD, of Health Interactions and funded by F. Hoffmann-La Roche, Ltd

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