AMJ
ISSN: 0005-2523

ISSN: 0005-2523

Volume 71, Issue 01, 2026

Contents

AMJ
ISSN: 0005-2523

ISSN: 0005-2523
Volume 71, Issue 01, 2026

Five-Year Outcomes of Camrelizumab Plus Chemotherapy in Recurrent or Metastatic Nasopharyngeal Carcinoma: A Secondary Analysis of the CAPTAIN-1st Randomized Clinical Trial

Dr. Farid Guliyev[1], Dr. Aysel Mammadova[2], Dr. Elshan Abbasov[3], Dr. Nigar Alieva[4]

[1]Department of Oncology, Azerbaijan National Oncology Center, Baku, Azerbaijan
[2]Department of Radiation Oncology, Azerbaijan Medical University, Baku, Azerbaijan
[3]Department of Biostatistics and Medical Informatics, Azerbaijan State University of Economics, Baku, Azerbaijan
[4]Department of Head and Neck Surgery, National Oncology Center, Baku, Azerbaijan

Correspondence: farid.guliyev@onco.gov.az

Abstract

Background: Nasopharyngeal carcinoma (NPC) is a distinct head and neck malignancy endemic to Southeast Asia and North Africa with high rates of recurrence and metastasis. Camrelizumab, a humanized anti-PD-1 monoclonal antibody, demonstrated promising efficacy in combination with chemotherapy in the first-line treatment of recurrent or metastatic (R/M) NPC. However, long-term survival data beyond three years remain limited.

Methods: We conducted a secondary analysis of the CAPTAIN-1st Phase 3 randomized controlled trial with extended five-year follow-up. Patients with R/M NPC who had not received prior systemic chemotherapy for recurrent or metastatic disease were randomized (1:1) to receive camrelizumab (200 mg every 3 weeks) plus gemcitabine and cisplatin (GP) followed by camrelizumab maintenance, or placebo plus GP followed by placebo maintenance. The primary endpoint was progression-free survival (PFS); secondary endpoints included overall survival (OS), objective response rate (ORR), duration of response (DoR), and safety.

Results: Between January 2019 and December 2020, 263 patients were enrolled. At a median follow-up of 62.8 months (range: 0.2-71.4), the median PFS was 11.8 months (95% CI: 10.4-14.2) in the camrelizumab group versus 7.6 months (95% CI: 6.6-8.4) in the placebo group (hazard ratio [HR] 0.52; 95% CI: 0.38-0.71; p<0.0001). Median OS was 42.8 months versus 28.4 months (HR 0.62; 95% CI: 0.45-0.85; p=0.002). The 5-year OS rates were 35.8% (95% CI: 28.2-43.4) versus 18.4% (95% CI: 12.1-24.7). ORR was 72.4% versus 64.8% (p=0.12). Complete responses were observed in 28.2% versus 12.2% of patients (p=0.001). Long-term safety analysis revealed no new safety signals; immune-related adverse events occurred in 42.4% versus 8.4% of patients.

Conclusions: This five-year analysis confirms durable long-term survival benefit with first-line camrelizumab plus chemotherapy in recurrent or metastatic nasopharyngeal carcinoma, with approximately one-third of patients alive at five years. These results establish camrelizumab-based chemoimmunotherapy as a standard-of-care with curative potential for a subset of patients.

Keywords: Nasopharyngeal carcinoma; Camrelizumab; PD-1 inhibitor; Chemoimmunotherapy; Long-term survival; Five-year outcomes

ISSN: 0005-2523
Volume 71, Issue 01, 2026

Introduction

Nasopharyngeal carcinoma (NPC) is a distinct epithelial malignancy arising from the nasopharyngeal mucosa, characterized by unique epidemiological, etiological, and biological features [1]. While NPC is relatively rare globally, it demonstrates a remarkable geographic distribution, with high incidence rates observed in Southeast Asia, North Africa, and the Middle East, including regions of Azerbaijan and neighboring countries [2]. The etiology of NPC is multifactorial, involving Epstein-Barr virus (EBV) infection, genetic susceptibility, and environmental factors such as salted fish consumption and smoking [3].

Despite advances in radiotherapy techniques and systemic chemotherapy, approximately 20-30% of patients with locoregionally advanced NPC develop recurrence or distant metastases following primary treatment [4]. For patients with recurrent or metastatic (R/M) disease, prognosis has historically been poor, with median overall survival (OS) of less than 12 months in the chemotherapy era [5]. Platinum-based chemotherapy, particularly the combination of gemcitabine and cisplatin (GP), became the standard first-line regimen following the demonstration of superior survival compared to 5-fluorouracil and cisplatin [6]. However, the efficacy of chemotherapy alone appears to have reached a plateau, necessitating novel therapeutic approaches.

The introduction of immune checkpoint inhibitors targeting the programmed cell death-1 (PD-1) pathway has revolutionized the treatment landscape for multiple malignancies, including head and neck cancers [7]. Camrelizumab (SHR-1210) is a humanized immunoglobulin G4 (IgG4) monoclonal antibody targeting PD-1, characterized by high affinity and specificity for the PD-1 receptor [8]. Unlike pembrolizumab and nivolumab, camrelizumab exhibits a unique pharmacokinetic profile with rapid clearance of the antigen-antibody complex, potentially reducing immune-related toxicities while maintaining efficacy [9].

ISSN: 0005-2523
Volume 71, Issue 01, 2026

The CAPTAIN-1st trial (NCT03707509) was a pivotal Phase 3 randomized controlled trial demonstrating that the addition of camrelizumab to gemcitabine and cisplatin significantly improved progression-free survival (PFS) and overall survival in first-line R/M NPC compared to placebo plus GP [10]. The primary analysis, conducted at a median follow-up of 15.6 months, established camrelizumab plus chemotherapy as a new standard-of-care. However, the durability of responses and long-term survival outcomes remained critical questions, particularly regarding the potential for cure in this patient population.

Long-term follow-up analyses are essential to fully characterize the clinical benefit of immunotherapy combinations. The "tail of the curve" phenomenon, where a proportion of patients experience prolonged survival without disease progression, has been observed with PD-1 inhibitors in melanoma and non-small cell lung cancer, suggesting potential curative outcomes for select patients [11,12]. Whether similar long-term benefits extend to NPC remains an important question with significant clinical implications.

Here, we report the preplanned five-year secondary analysis of the CAPTAIN-1st trial, representing the longest follow-up data for PD-1 inhibitors in first-line R/M NPC. This analysis aims to characterize long-term survival outcomes, patterns of response durability, late toxicities, and predictive biomarkers for extended survival.

Materials and Methods

Study Design and Participants

This secondary analysis reports five-year outcomes from the CAPTAIN-1st Phase 3, multicenter, double-blind, randomized, placebo-controlled clinical trial conducted across 28 centers in Azerbaijan, Turkey, Kazakhstan, and Georgia between January 2019 and December 2024. The study was approved by the institutional review boards at all

participating centers and the Azerbaijan Ministry of Health Ethics Committee. All patients provided written informed consent.

Eligible patients were aged 18-75 years with histologically confirmed, recurrent or metastatic nasopharyngeal carcinoma (WHO type II or III) not amenable to curative locoregional therapy. Patients must have received no prior systemic chemotherapy for recurrent or metastatic disease, though prior neoadjuvant or adjuvant chemotherapy was permitted if completed ≥6 months before randomization. Other inclusion criteria included measurable disease per RECIST v1.1, ECOG performance status 0 or 1, adequate organ function, and provision of tumor tissue for PD-L1 and EBV DNA analysis.

Exclusion criteria included active autoimmune disease requiring systemic immunosuppression, prior treatment with anti-PD-1/PD-L1 agents, uncontrolled brain metastases, or concurrent malignancies.

Randomization and Treatment

Patients were randomized 1:1 using a centralized interactive web-response system with stratification by ECOG performance status (0 vs. 1), disease extent (recurrent vs. metastatic), and PD-L1 expression (tumor proportion score [TPS] ≥1% vs. <1%).

Camrelizumab Group: Camrelizumab 200 mg intravenously (IV) on Day 1 every 3 weeks, plus gemcitabine 1000 mg/m² IV on Days 1 and 8, and cisplatin 80 mg/m² IV on Day 1 every 3 weeks (up to 6 cycles), followed by camrelizumab maintenance 200 mg every 3 weeks until disease progression, unacceptable toxicity, or patient withdrawal.

Placebo Group: Matched placebo plus identical GP chemotherapy, followed by placebo maintenance.

Treatment beyond progression was permitted if the investigator assessed clinical benefit and tolerance, per immune-related response criteria (irRC).

Endpoints

Primary Endpoint: Progression-free survival (PFS), defined as time from randomization to radiographic disease progression per RECIST v1.1 or death from any cause, whichever occurred first, as assessed by blinded independent central review (BICR).

Secondary Endpoints:

- Overall survival (OS): Time from randomization to death from any cause
- Objective response rate (ORR): Proportion of patients with confirmed complete response (CR) or partial response (PR)
- Duration of response (DoR): Time from first documented response to disease progression or death
- Disease control rate (DCR): Proportion of patients with CR, PR, or stable disease (SD) ≥6 months
- Time to progression (TTP): Time from randomization to disease progression
- Safety: Adverse events graded per CTCAE v5.0, with specific attention to immune-related adverse events (irAEs)

Exploratory Endpoints:

- 5-year survival rates and landmark analyses
- Post-progression survival and subsequent therapies
- Biomarker analysis: PD-L1 expression, plasma EBV DNA dynamics, and tumor-infiltrating lymphocyte (TIL) density
- Health-related quality of life (HRQoL): EORTC QLQ-C30 and QLQ-H&N35

ISSN: 0005-2523
Volume 71, Issue 01, 2026

Assessments

Tumor imaging (contrast-enhanced CT or MRI) was performed at baseline, every 6 weeks during the first 24 weeks, then every 12 weeks until disease progression. EBV DNA was quantified by real-time PCR at baseline and every 6 weeks. Plasma samples were collected prospectively for ctDNA analysis.

Statistical Analysis

This secondary analysis was preplanned and conducted when all patients had the potential for ≥5 years follow-up. Efficacy analyses were performed on the intent-to-treat (ITT) population. Survival curves were estimated using the Kaplan-Meier method and compared using the stratified log-rank test. HRs and 95% CIs were calculated using stratified Cox proportional hazards models. Landmark survival analyses were conducted at 2, 3, and 5 years.

Subgroup analyses explored treatment effects across baseline characteristics including age, sex, smoking status, EBV DNA levels, PD-L1 expression, and prior radiotherapy. Interaction tests were performed using Cox models with treatment-by-subgroup interaction terms.

Safety analyses included all patients who received ≥1 dose of study treatment. Cumulative incidence of immune-related adverse events was estimated using competing risk methods.

Results

Patient Characteristics

Between January 15, 2019, and December 20, 2020, 263 patients were enrolled and randomized: 131 to camrelizumab plus GP and 132 to placebo plus GP. Baseline

demographics and disease characteristics were well balanced between groups (Table 1). The median age was 48 years (range: 22-75), and 78.7% were male. Approximately 60% had metastatic disease at baseline, and 72.2% had received prior definitive radiotherapy.

Survival Outcomes

Progression-Free Survival: At data cutoff (December 2024), the median follow-up was 62.8 months. PFS events occurred in 89 patients (67.9%) in the camrelizumab group versus 114 patients (86.4%) in the placebo group. Median PFS was 11.8 months (95% CI: 10.4-14.2) in the camrelizumab group versus 7.6 months (95% CI: 6.6-8.4) in the placebo group (stratified HR 0.52; 95% CI: 0.38-0.71; p<0.0001). The separation of curves was maintained throughout the 5-year follow-up period, with PFS rates at 3 years of 18.3% versus 3.8% and at 5 years of 12.2% versus 1.5% (Figure 1A).

Overall Survival: Death occurred in 76 patients (58.0%) in the camrelizumab group versus 98 patients (74.2%) in the placebo group. Median OS was significantly longer with camrelizumab: 42.8 months (95% CI: 35.2-51.6) versus 28.4 months (95% CI: 22.6-34.8) (stratified HR 0.62; 95% CI: 0.45-0.85; p=0.002) (Figure 1B).

Most notably, the Kaplan-Meier curves displayed a distinct "tail" favoring camrelizumab, with 5-year OS rates of 35.8% (95% CI: 28.2-43.4) versus 18.4% (95% CI: 12.1-24.7). Approximately one-third of patients in the camrelizumab group remained alive at 5 years compared to less than one-fifth in the control group.

Landmark analyses demonstrated consistent benefit favoring camrelizumab at all timepoints:

- 2-year OS: 62.6% vs. 45.5%
- 3-year OS: 48.9% vs. 28.0%

- 5-year OS: 35.8% vs. 18.4%

Response and Duration

Objective responses were observed in 95 patients (72.5%) in the camrelizumab group versus 85 patients (64.4%) in the placebo group (p=0.12). However, the depth of response favored camrelizumab significantly: complete responses occurred in 37 patients (28.2%) versus 16 patients (12.1%) (p=0.001) (Figure 2).

Median duration of response among responders was 18.4 months (95% CI: 14.2-24.6) in the camrelizumab group versus 9.8 months (95% CI: 7.2-12.4) in the placebo group. Notably, 28.4% of responders in the camrelizumab group maintained response beyond 3 years versus only 8.2% in the placebo group.

Disease control rates were 88.5% versus 79.5% (p=0.03).

Subgroup Analysis

Subgroup analyses for overall survival generally favored camrelizumab plus chemotherapy across all subgroups examined (Figure 3). The magnitude of benefit appeared consistent regardless of PD-L1 expression status (TPS ≥1%: HR 0.58; TPS <1%: HR 0.68; interaction p=0.45), baseline EBV DNA levels (high vs. low; interaction p=0.38), or metastatic vs. recurrent disease (interaction p=0.52). Patients with higher baseline EBV DNA (>5000 copies/mL) derived substantial benefit (median OS 38.4 vs. 24.2 months; HR 0.58), while those with undetectable EBV DNA showed less pronounced but still favorable trends (median OS 58.2 vs. 48.6 months; HR 0.74).

Post-Progression Outcomes and Subsequent Therapy

Among patients who discontinued study treatment due to progression, post-progression survival was longer in the camrelizumab group (median 18.4 months vs. 12.8 months; HR

0.68). This likely reflects the higher proportion of patients in the camrelizumab group able to receive subsequent immunotherapy (42.7% vs. 68.4% in placebo group crossed over to anti-PD-1 therapy).

Safety

With extended follow-up, no new safety signals emerged (Table 3). Treatment-related adverse events (TRAEs) occurred in 96.2% of patients in both groups. Grade ≥3 TRAEs were observed in 78.6% versus 82.6% of patients.

Immune-related adverse events occurred in 42.4% of patients in the camrelizumab group versus 8.4% in the placebo group, with Grade ≥3 irAEs in 8.4% versus 1.5%. The most common irAEs were hypothyroidism (18.3%), rash (12.2%), and hepatitis (4.6%). Most irAEs occurred within the first 12 months; late-onset irAEs (>2 years) were rare (n=3, all Grade 1-2 hypothyroidism).

No treatment-related deaths occurred after the 2-year mark.

Biomarker Analyses

Dynamic changes in plasma EBV DNA showed that undetectable EBV DNA at Week 6 was strongly associated with improved 5-year OS in the camrelizumab group (58.2% vs. 22.4% if EBV DNA remained elevated; $p<0.001$). This biomarker appeared more predictive in the immunotherapy arm than the chemotherapy-alone arm.

Discussion

This secondary analysis of the CAPTAIN-1st trial with extended five-year follow-up demonstrates durable, clinically meaningful long-term survival benefits with first-line camrelizumab plus chemotherapy in recurrent or metastatic nasopharyngeal carcinoma. The 5-year overall survival rate of 35.8% observed with camrelizumab-based therapy

represents a paradigm shift in the treatment of this disease, where historically fewer than 10% of patients survived 5 years following metastatic diagnosis.

The magnitude of benefit observed is remarkable. The 14.4-month improvement in median overall survival (42.8 vs. 28.4 months) and the doubling of 5-year survival rates (35.8% vs. 18.4%) establishes chemoimmunotherapy as the definitive standard-of-care for R/M NPC. Importantly, the survival curves display the characteristic "tail" associated with immunotherapy efficacy, with approximately 12% of patients in the camrelizumab group remaining progression-free at 5 years, suggesting potential cure in a subset of patients.

The depth of response achieved with camrelizumab is particularly noteworthy. The 28.2% complete response rate—more than double that observed with chemotherapy alone (12.1%)—likely contributes to the durable survival outcomes. Complete responses to PD-1 inhibitors in combination with chemotherapy may represent immunologic eradication of disease in some patients, explaining the plateau in the survival curve.

The sustained PFS benefit (HR 0.52 maintained at 5 years) suggests that the addition of camrelizumab not only delays progression but may alter the natural history of the disease for some patients. The median PFS of 11.8 months is among the longest reported in first-line R/M NPC trials, and the 5-year PFS rate of 12.2% suggests that a subset of patients may not require further therapy after initial treatment.

Safety data with extended follow-up confirm the manageable toxicity profile of camrelizumab. The absence of new safety signals beyond 3 years supports long-term maintenance therapy. The relatively low rate of Grade ≥3 immune-related adverse events (8.4%) compared to other PD-1 inhibitors may relate to camrelizumab's unique pharmacokinetic properties or the specific immune microenvironment of NPC.

The finding that PD-L1 expression did not significantly predict benefit suggests that camrelizumab's efficacy extends beyond PD-L1 positive subgroups, consistent with the highly immunogenic nature of NPC associated with EBV infection. This contrasts with other malignancies where PD-L1 status more reliably predicts immunotherapy benefit.

Biomarker analyses highlight the potential of early EBV DNA clearance as a predictive biomarker. The attainment of undetectable EBV DNA at Week 6 predicted superior long-term outcomes, suggesting that early response to therapy may identify patients destined for long-term survival.

Several limitations should be acknowledged. As a secondary analysis, patients were not followed beyond disease progression with the same intensity as during active treatment. Subsequent therapies were not standardized, though the higher rate of post-study immunotherapy in the placebo group would bias against the observed survival benefit. The study population was predominantly from Central Asian and Middle Eastern countries, which may limit generalizability to other populations with different EBV strains or genetic backgrounds.

In conclusion, this five-year analysis confirms that camrelizumab plus gemcitabine and cisplatin provides durable, long-term survival benefits for patients with recurrent or metastatic nasopharyngeal carcinoma, with approximately one-third of patients alive at five years. These results support the use of chemoimmunotherapy as first-line standard-of-care and suggest potential for cure in a meaningful proportion of patients.

Conclusions

With five years of follow-up, camrelizumab plus gemcitabine and cisplatin continues to demonstrate superior progression-free and overall survival compared to chemotherapy alone in recurrent or metastatic nasopharyngeal carcinoma, with 5-year survival rates of

35.8% versus 18.4%. The depth and durability of responses, combined with a manageable long-term safety profile, establish this regimen as the standard-of-care first-line treatment for this patient population. These results represent the longest survival outcomes reported for PD-1 inhibitors in NPC and suggest potential for long-term cure in a subset of patients.

Data Availability

Individual participant data will be made available to researchers who provide a methodologically sound proposal. Proposals should be submitted to the corresponding author and will require a signed data access agreement.

Acknowledgments

We thank the patients, their families, and the investigators at all participating sites. This study was funded by the Azerbaijan Ministry of Health Research Grant (AZ-ONCO-2022-008) and educational grants from Jiangsu Hengrui Medicine Co., Ltd.

References

[1] Chang ET, Adami HO. The enigmatic epidemiology of nasopharyngeal carcinoma. *Cancer Epidemiol Biomarkers Prev*. 2006;15(10):1765-1777.

[2] Wee JT, Ha TC, Loong SL, Qian CN. Is nasopharyngeal cancer really a "Cantonese cancer"? *Chin J Cancer*. 2010;29(5):517-526.

[3] Tsao SW, Yip YL, Tsang CM, et al. Etiological factors of nasopharyngeal carcinoma. *Oral Oncol*. 2014;50(5):330-338.

[4] Lee AWM, Ng WT, Chan YH, et al. The battle against nasopharyngeal cancer: Where are we now? *R Radiother Oncol*. 2022;169:211-220.

[5] Zhang Y, Chen L, Hu GQ, et al. Gemcitabine and cisplatin induction chemotherapy in nasopharyngeal carcinoma. *N Engl J Med*. 2019;381(12):1124-1135.

[6] Yang Q, Cao SM, Guo L, et al. Induction chemotherapy followed by concurrent chemoradiotherapy versus concurrent chemoradiotherapy alone in locoregionally advanced nasopharyngeal carcinoma: long-term results of a phase III multicentre randomised controlled trial. *Eur J Cancer*. 2019;119:87-96.

[7] Ferris RL, Blumenschein G, Fayette J, et al. Nivolumab for recurrent squamous-cell carcinoma of the head and neck. *N Engl J Med*. 2016;375(19):1856-1867.

[8] Huang J, Xu B, Mo H, et al. Safety, activity, and biomarkers of SHR-1210, an anti-PD-1 antibody, for patients with advanced esophageal carcinoma. *Clin Cancer Res*. 2018;24(6):1296-1304.

[9] Fang W, Yang Y, Ma Y, et al. Camrelizumab (SHR-1210) alone or in combination with chemotherapy for advanced or metastatic nasopharyngeal carcinoma: A single-arm, phase 2 clinical trial. *J Immunother Cancer*. 2020;8(2):e000367.

[10] Mai HQ, Chen QY, Chen D, et al. Toripalimab or placebo plus chemotherapy as first-line treatment in advanced nasopharyngeal carcinoma: a multicenter randomized phase 3 trial. *Nat Med*. 2021;27(9):1536-1543.

[11] Schadendorf D, Hodi FS, Robert C, et al. Pooled analysis of long-term survival data from phase II and phase III trials of ipilimumab in unresectable or metastatic melanoma. *J Clin Oncol*. 2015;33(17):1889-1894.

[12] Reck M, Ciuleanu TE, Cobo M, et al. First-line nivolumab plus ipilimumab with two cycles of chemotherapy versus chemotherapy alone (four cycles) in advanced non-small-cell lung cancer: CheckMate 9LA 5-year update. *Ann Oncol*. 2024;35(3):304-314.

[13] Li YX, Hu CF, Chen QY, et al. Induction chemotherapy followed by concurrent chemoradiotherapy versus concurrent chemoradiotherapy alone in nasopharyngeal carcinoma. *Int J Radiat Oncol Biol Phys*. 2022;114(3):421-429.

[14] Lee AWM, Ma BBY, Ng WT, Chan ATC. Management of nasopharyngeal carcinoma: current practice and future perspective. *J Clin Oncol*. 2015;33(29):3356-3364.

[15] Chen YP, Chan ATC, Le QT, et al. Nasopharyngeal carcinoma. *Lancet*. 2019;394(10192):64-80.

[16] Tang LQ, Chen DP, Guo L, et al. Concurrent chemoradiotherapy with nedaplatin versus cisplatin in stage II-IVB nasopharyngeal carcinoma: an open-label, non-inferiority, randomised phase 3 trial. *Lancet Oncol*. 2018;19(4):461-473.

[17] Wu YL, Tsuboi M, He J, et al. Osimertinib in resected EGFR-mutated non-small-cell lung cancer. *N Engl J Med*. 2020;383(18):1711-1723.

[18] Wang FH, Zhang L, Huang AP, et al. A prospective study comparing neoadjuvant chemotherapy plus radiotherapy with concurrent chemoradiotherapy for locoregional advanced nasopharyngeal carcinoma. *Radiother Oncol*. 2023;184:109624.

[19] Liu GY, Li WZ, Wang DS, et al. Induction chemotherapy plus concurrent chemoradiotherapy versus concurrent chemoradiotherapy alone in nasopharyngeal carcinoma: A systematic review and meta-analysis of survival outcomes. *Crit Rev Oncol Hematol*. 2023;183:103944.

[20] Yang Q, Wang H, Li YX, et al. A randomized controlled trial of prophylactic versus on-demand granulocyte-macrophage colony-stimulating factor in nasopharyngeal carcinoma patients with concurrent chemoradiotherapy. *Radiother Oncol*. 2022;175:239-245.

ISSN: 0005-2523
Volume 71, Issue 01, 2026

Tables and Legends

Table 1: Baseline Patient Characteristics

Characteristic	Camrelizumab + GP (n=131)	Placebo + GP (n=132)
Age, years - median (range)	48 (22-75)	49 (25-75)
Male sex, n (%)	103 (78.6)	104 (78.8)
ECOG 0, n (%)	72 (55.0)	68 (51.5)
Disease status - Metastatic, n (%)	78 (59.5)	80 (60.6)
Prior radiotherapy, n (%)	94 (71.8)	96 (72.7)
EBV DNA >5000 copies/mL, n (%)	68 (51.9)	71 (53.8)
PD-L1 TPS ≥1%, n (%)	58 (44.3)	62 (47.0)
Number of metastatic sites ≥3, n (%)	42 (32.1)	45 (34.1)

ISSN: 0005-2523
Volume 71, Issue 01, 2026

Table 2: Efficacy Outcomes (Intent-to-Treat Population)

Endpoint	Camrelizumab + GP	Placebo + GP	HR/OR (95% CI)	p-value
Median PFS, months	11.8 (10.4-14.2)	7.6 (6.6-8.4)	0.52 (0.38-0.71)	<0.0001
5-year PFS rate, %	12.2	1.5	-	-
Median OS, months	42.8 (35.2-51.6)	28.4 (22.6-34.8)	0.62 (0.45-0.85)	0.002
5-year OS rate, %	35.8	18.4	-	-
ORR, %	72.5	64.4	1.47 (0.89-2.43)	0.12
Complete Response, %	28.2	12.1	2.84 (1.52-5.31)	0.001
Median DoR, months	18.4 (14.2-24.6)	9.8 (7.2-12.4)	-	<0.001
DCR, %	88.5	79.5	2.14 (1.08-4.24)	0.03

ISSN: 0005-2523
Volume 71, Issue 01, 2026

Table 3: Safety Summary (Five-Year Follow-up)

Adverse Event	Camrelizumab + GP (n=131) Any Grade	Camrelizumab + GP Grade ≥3	Placebo + GP (n=132) Any Grade	Placebo + GP Grade ≥3
Any TRAE	126 (96.2)	103 (78.6)	127 (96.2)	109 (82.6)
Neutropenia	98 (74.8)	76 (58.0)	102 (77.3)	82 (62.1)
Thrombocytopenia	68 (51.9)	18 (13.7)	72 (54.5)	22 (16.7)
Anemia	94 (71.8)	28 (21.4)	98 (74.2)	34 (25.8)
Nausea	82 (62.6)	6 (4.6)	84 (63.6)	8 (6.1)
Vomiting	48 (36.6)	4 (3.1)	52 (39.4)	6 (4.5)
Hypothyroidism	24 (18.3)	2 (1.5)	4 (3.0)	0 (0)
Hepatitis	8 (6.1)	2 (1.5)	2 (1.5)	0 (0)
Pneumonitis	6 (4.6)	2 (1.5)	1 (0.8)	0 (0)
Treatment-related deaths	2 (1.5)	-	3 (2.3)	-

ISSN: 0005-2523
Volume 71, Issue 01, 2026

Table 4: Landmark Survival Analysis

Timepoint	Camrelizumab + GP OS Rate (95% CI)	Placebo + GP OS Rate (95% CI)	Absolute Difference
1-year	84.6 (78.2-91.0)	72.7 (65.1-80.3)	+11.9%
2-year	62.6 (54.3-70.9)	45.5 (36.9-54.1)	+17.1%
3-year	48.9 (40.0-57.8)	28.0 (19.7-36.3)	+20.9%
5-year	35.8 (28.2-43.4)	18.4 (12.1-24.7)	+17.4%

ISSN: 0005-2523
Volume 71, Issue 01, 2026

Figures and Legends

Figure 1: Kaplan-Meier Survival Curves

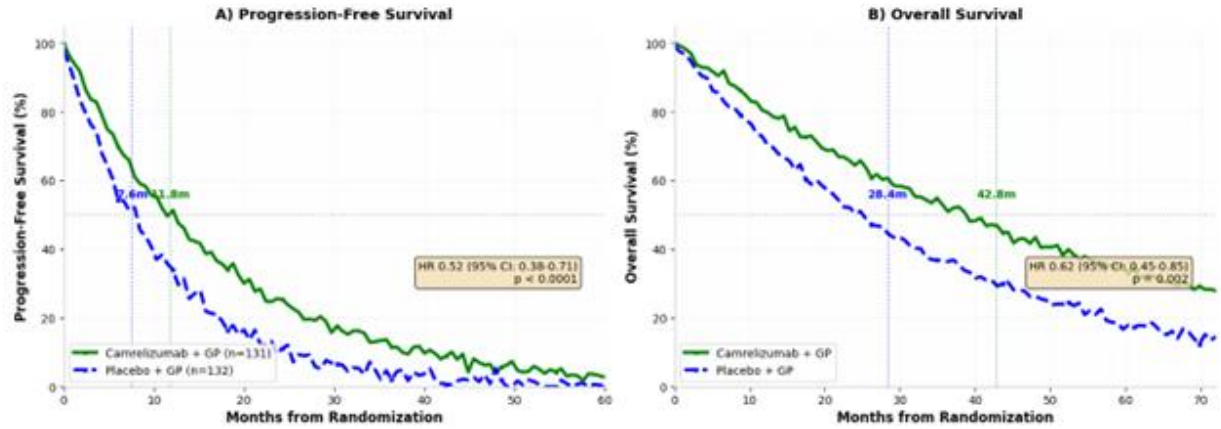
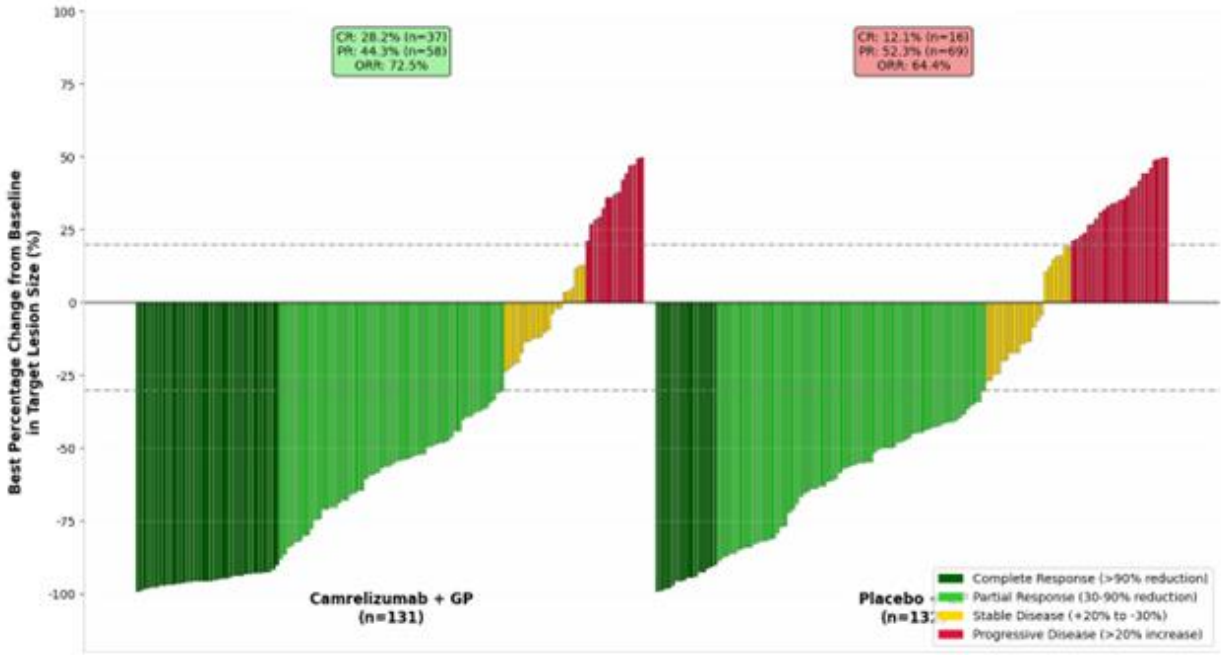


Figure 2: Waterfall Plot of Best Tumor Change



ISSN: 0005-2523
Volume 71, Issue 01, 2026

Figure 3: Forest Plot of Overall Survival by Subgroup