

P2.100: Prolgolimab with chemo as 1st line therapy for patients with advanced nsNSCLC: extended 36 months follow-up of phase III trial DOMAJOR

E. Moiseenko¹, K. Laktionov², D. Stroyakovsky³, H.Liu⁴, V. Moiseenko¹, M. Dvorkin⁵, T. Andabekov⁶, A.Smolin⁷, V. Kozlov⁸, S. Odintsova⁹, S. Dvoretzky¹⁰, A. Mochalova¹¹, M. Urda¹², U. László¹³, V. Müller¹⁴, K. Bogos¹⁵, N. Fadeeva¹⁶, G. Musaev¹⁷, D. Kirtbaya¹⁸, O. Gladkov¹⁹, M. Narimanov²⁰, T. Semiglazova²¹, A. Khasanova²², J. Chovanec²³, I. Andrasina²⁴, A. Szabová²⁵, O. Rosinská²⁶, D. Sudekova²⁷, P.S. Zsolt²⁸, A. Pirmagomedov²⁹, E. Poddubskaya³⁰, N. Kislov³¹, I. Shumskaya³², I. Metkechekova³³, N. Tkachenko³³
¹SBHI "N.P. Napalkov St. Petersburg Clinical Scientific and Practical Center for Specialized Types of Medical Care (Oncology)", St. Petersburg/RU, ²FSBI "N.N.Blokhin National Medical Research Center of Oncology" of the Russian Ministry of Health, Moscow/RU, ³Moscow City Oncology Hospital No. 62, Moscow/RU, ⁴Jilin Cancer Hospital, Changchun/CN, ⁵BHI "Clinical Oncology Dispensary", Omsk/RU, ⁶Limited Liability Company AV Medical Group, St. Petersburg/RU, ⁷FSBI "Academician N.N. Burdenko Main Military Clinical Hospital", MoH, Moscow/RU, ⁸SBHI "Novosibirsk Regional Clinical Oncology Dispensary", Novosibirsk/RU, ⁹ISC Modern Medical Technologies, St. Petersburg/RU, ¹⁰FSBEI of Higher Education "Academician I.P. Pavlov First St. Petersburg State Medical University", St. Petersburg/RU, ¹¹JSC Medsi Group of Companies, Moscow/RU, ¹²F.D. Roosevelt Faculty Hospital with Polyclinic in Banska Bistrica (Fakultná nemocnica s poliklinikou F. D. Rooseveltta), Banska Bystrica/SK, ¹³Mátrai Gyógyintézet,Mátraháza/HU, ¹⁴Semmelweis Egyetem Pulmonológiai Klinika,Budapest/HU, ¹⁵Országos Korányi Pulmonológiai Intézet IVTüdőbelsztály, Budapest/HU, ¹⁶SBHI "Chelyabinsk Regional Clinical Center of Oncology and Nuclear Medicine", Chelyabinsk/RU, ¹⁷FSBI "National Medical and Surgical Center named after N.I. Pirogov", MoH, Moscow/RU, ¹⁸SBHI "Oncology Dispensary No. 2", Sochi/RU, ¹⁹Limited Liability Company EVIMED, Chelyabinsk/RU, ²⁰SBHI "Podolsk Regional Clinical Hospital", Podolsk/RU, ²¹FSBI "N.N.Petrov National Medical Research Center for Oncology", MoH, St.Petersburg/RU, ²²SAHI "M.Z. Sigal Republican Clinical Oncology Dispensary of the Ministry of Health of the Republic of Tatarstan", Kazan/RU, ²³Nemocnica s poliklinikou Sv. Jakuba, Bardejov/SK, ²⁴Východoslovenský onkologický ústav, a.s. Nemocničná lekárň VITA, Kosice/SK, ²⁵Nemocnica na okraji mesta, n.o. Onkologická ambulancia, Partizánske/SK, ²⁶Nemocnica Komárno s.r.o. Oddelenie klinickej onkológie, Komárno/SK, ²⁷Fakultná nemocnica s poliklinikou Zilina Klinická a radiačná onkológia, Zilina/SK, ²⁸Fejér Megyei Szent György Egyetemi Oktatókórház Pulmonológia, Székesfehérvár/HU, ²⁹SBHI "Municipal Clinical Hospital No. 1", alchik/RU, ³⁰FSAEI of Higher Education I.M. Sechenov First Moscow Medical University, MoH, Moscow/RU, ³¹SBHI "Regional Clinical Oncology Hospital", Yaroslavl/RU, ³²SBHI "Nizhny Novgorod Regional Clinical Oncology Dispensary", Nizhny Novgorod/RU, ³³JSC Biocad, St. Petersburg/RU

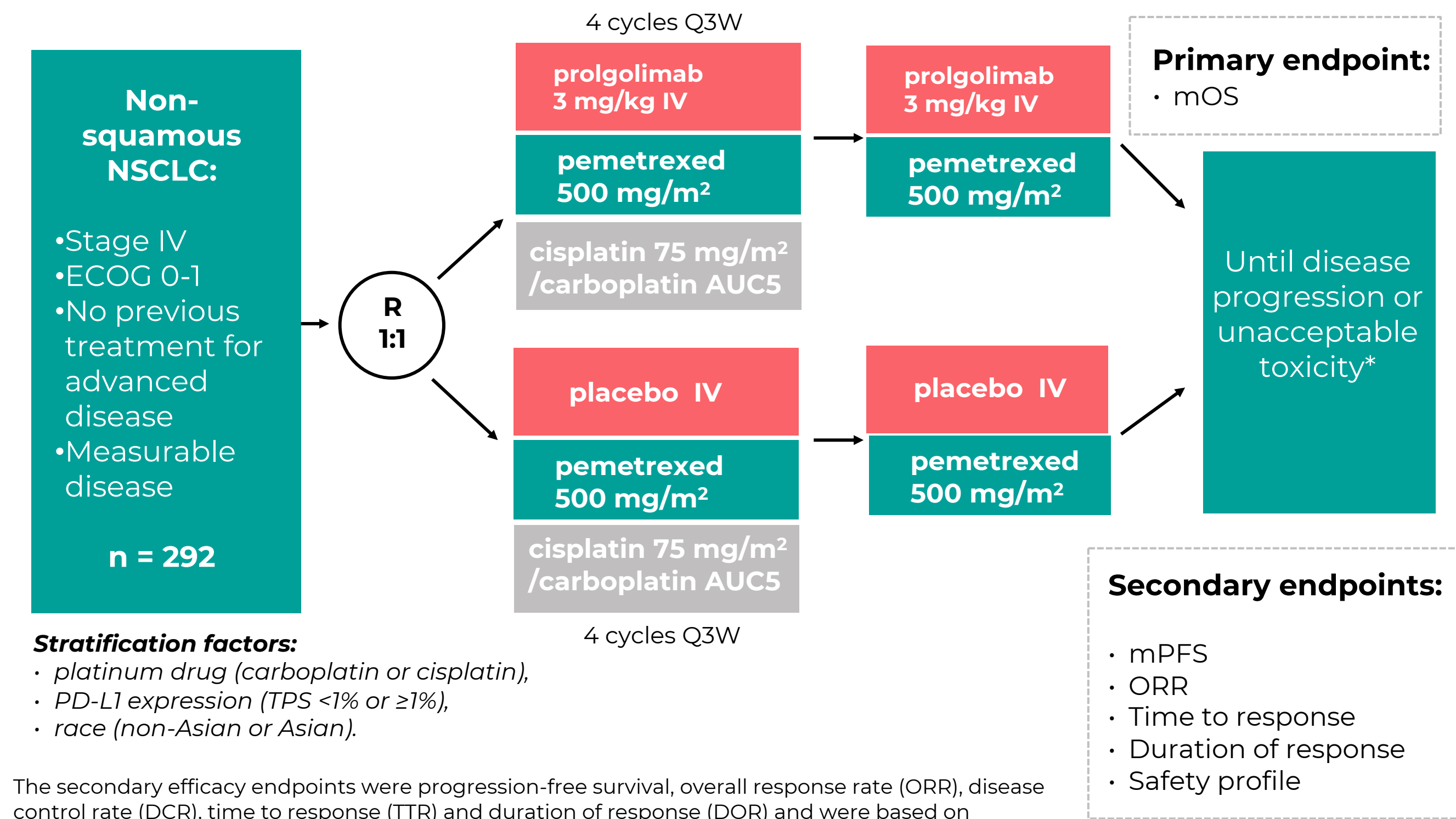
BACKGRAUND

Prolgolimab is an IgG1-based anti-PD-1 antibody with a Fc-silencing 'LALA' mutation¹. The phase III DOMAJOR trial (ClinicalTrials.gov identifier: NCT03912389) has previously demonstrated superior efficacy of prolgolimab plus pemetrexed with platinum-based chemotherapy (prolgolimab-combination group) over placebo plus pemetrexed with platinum-based chemotherapy (placebo-combination group)². This analysis assessed long-term efficacy (overall survival) and safety, along with subgroup analyses by stratification factors, including race and PD-L1 expression.

METHODS

Eligible patients were randomly assigned (1:1) to receive either prolgolimab 3 mg/kg or placebo, both as intravenous infusions every 3 weeks until progression or signs of unacceptable toxicity (up to 36 months after the start of study therapy) in combination with pemetrexed and cisplatin/carboplatin. Randomization was stratified according to platinum chemotherapy (carboplatin or cisplatin), PD-L1 expression (TPS <1% or ≥1%), and race (non-Chinese or Chinese).

STUDY DESIGN



STATISTICS

The sample size for superiority hypothesis was estimated such that 113 events of death would provide the trial with 80 % power to detect a HR of 0.59 for the comparison between the prolgolimab-combination group and the placebo-combination group at a one-sided alpha of 0.025.

Primary Endpoint: Overall Survival

Figure 1. Overall survival. Full Analysis Set

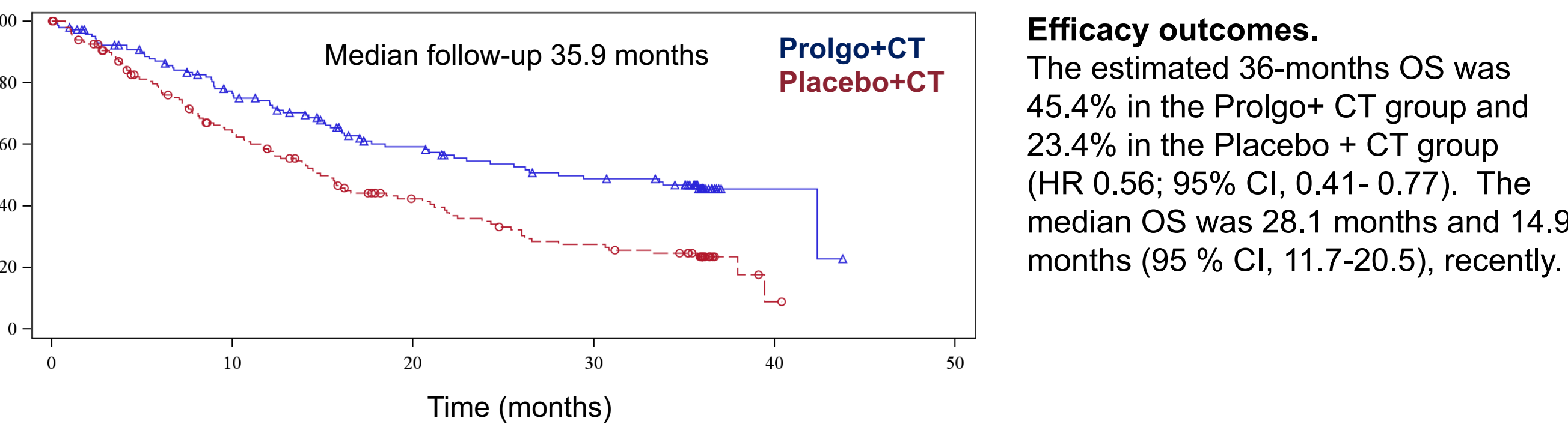
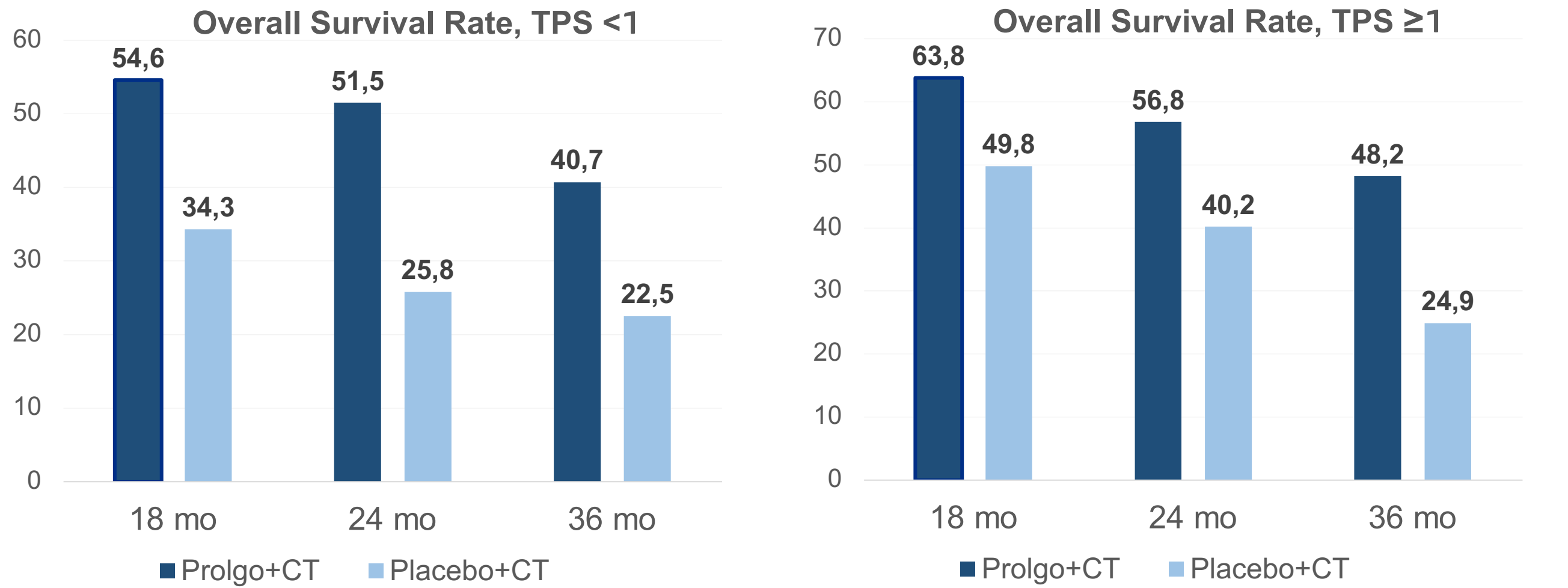


Figure 2. Overall Survival. Subgroup analysis by level of PD-L1 expression at baseline (TPS < 1%, TPS ≥ 1%). Full Analysis Set



RESULTS

Demographics and baseline characteristics of the main disease in ITT population were generally well balanced between the groups.

Table 1A. Baseline characteristics.

	PROLGO + CT (n = 143)	Placebo + CT (n = 149)
Age, n (%)		
>=18 to <65 years old	91 (63.6)	91 (61.1)
>=65 to <75 years	46 (32.2)	48 (32.2)
>=75 years	6 (4.2)	10 (6.7)
Sex, n (%)		
Female	48 (33.6)	42 (28.2)
Male	95 (66.4)	107 (71.8)
Race, n (%)		
Caucasian (non-Asian)	98 (68.5)	105 (70.5)
Asian	45 (31.5)	44 (29.5)
Smoking, n (%)		
Current/history	99 (69.2)	109 (73.2)
Non-smokers	44 (30.8)	40 (26.8)
ECOG status, n (%)		
0	40 (28)	37 (24.8)
1	103 (72)	112 (75.2)
PD-L1 status, n (%)		
TPS <1%	57 (39.9)	60 (40.3)
TPS ≥1%	86 (60.1)	89 (59.7)

Between September 2019, and November 2022, 292 patients were randomly assigned to the prolgolimab-combination group or the placebo-combination group at centers in Russia, China and Europe.

Secondary Endpoints: Progression Free Survival, ORR and Safety

Figure 3. Progression Free Survival. Full Analysis Set

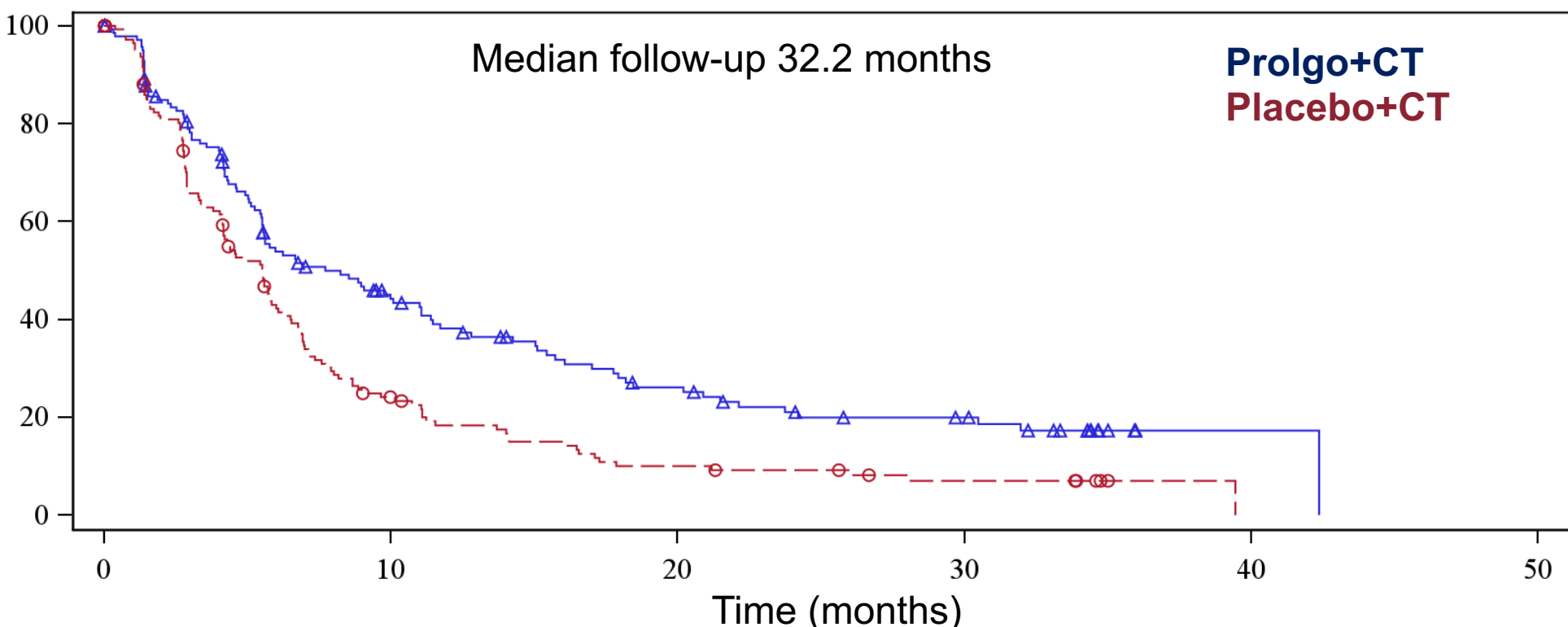


Figure 4. Progression Free Survival. Subgroup analysis by level of PD-L1 expression at baseline (TPS < 1%, TPS ≥ 1%). Full Analysis Set

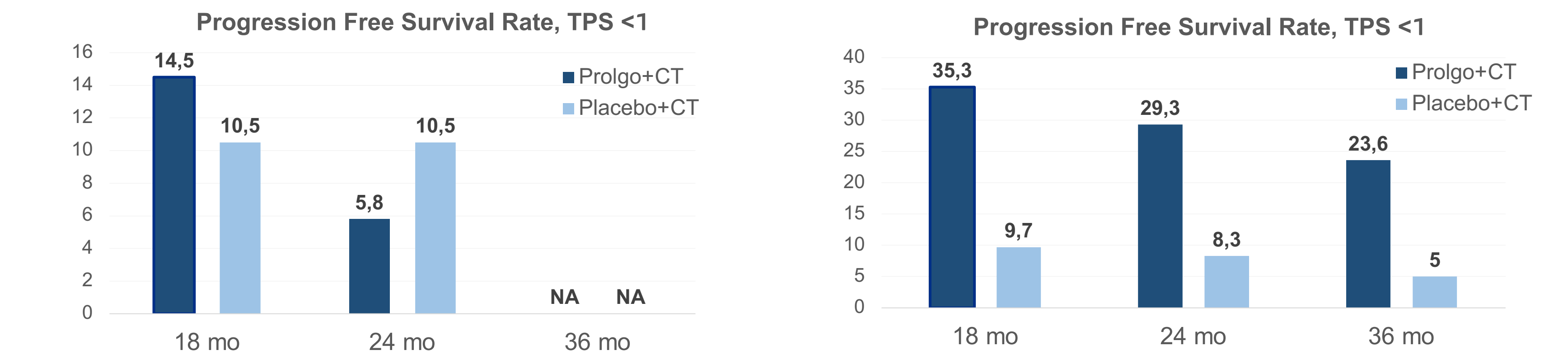


Table 3. Safety parameters. Safety Analysis Set.

Proportion of patients	PROLGO + CT n = 143, (%)	PLACEBO + CT n = 149, (%)
Adverse Events (all grades)		
AEs (grades 3-4)	90 (62,9)	61 (41,2)
Adverse Reactions (all grades)		
ARs (grades 3-4)	35 (24,5)	13 (8,8)
irAE (all grades)		
Treatment discontinuation due to AE	20 (14,0)	11 (7,4)
AEs (grade 5)	13 (9,1)	16 (10,8)
ARs (grade 5)	2 (1,4)	0

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Sponsored by JSC BIOCAD. Corresponding author: Fedor Moiseenko moiseenkofv@gmail.com

Table 1B. Baseline characteristics.

	PROLGO + CT (n = 143)	Placebo + CT (n = 149)
Histological type of tumor, n (%)		
Adenocarcinoma	96 (97.0)	103 (98.1)
Large cell carcinoma	3 (3.0)	2 (1.9)
Presence of MTS, %		
143 (100)	95 (100)	
Number of organs with MTS		
Median	3	3
Minimum	1	1
Maximum	8	10
Organs with metastases, n (%)		
bones	63 (44.1)	47 (31.5)
liver	23 (16.1)	22 (14.8)
lung	90 (62.9)	106 (71.1)
brain	15 (10.5)	23 (15.4)
peritoneum	1 (1)	2 (1.3)
lymph nodes	109 (76.2)	128 (85.9)
adrenal gland	29 (20.3)	42 (28.2)
other	65 (45.5)	61 (40.9)

Table 2. Response to therapy per RECIST 1.1. Full Analysis Set.

Best overall response (95% CI)	PROLGO + CT	PLACEBO + CT
CR (%)	0.7	0
PR (%)	49.7	27.5
SD (%)	30.1	46.3
PD (%)	11.2	12.8
NE (%)	7.7	12.8
ND (%)	0.7	0

Figure 5. Overall Survival. Subgroup analysis by race and level of PD-L1 expression at baseline (TPS < 1%, TPS ≥1%). Full Analysis Set

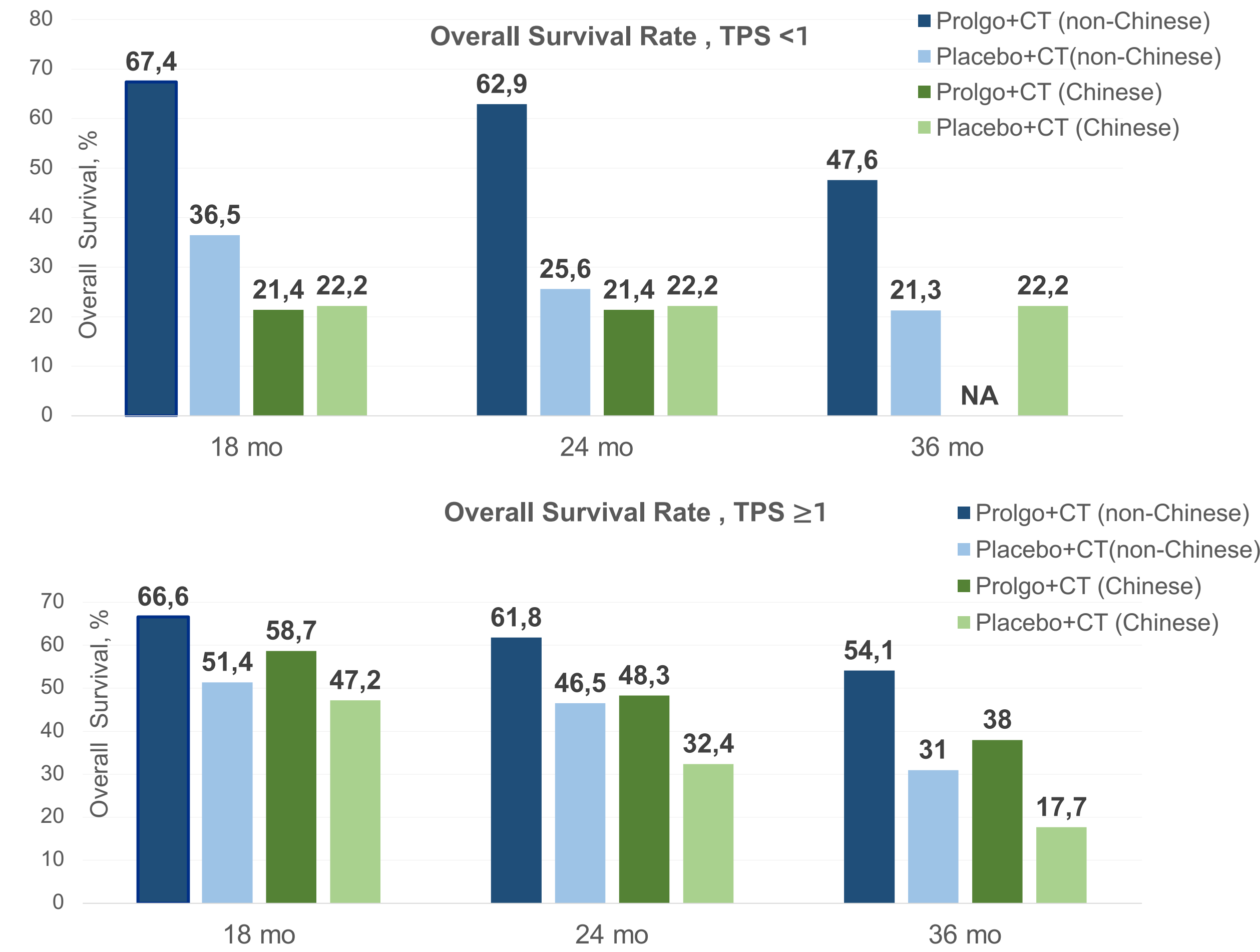
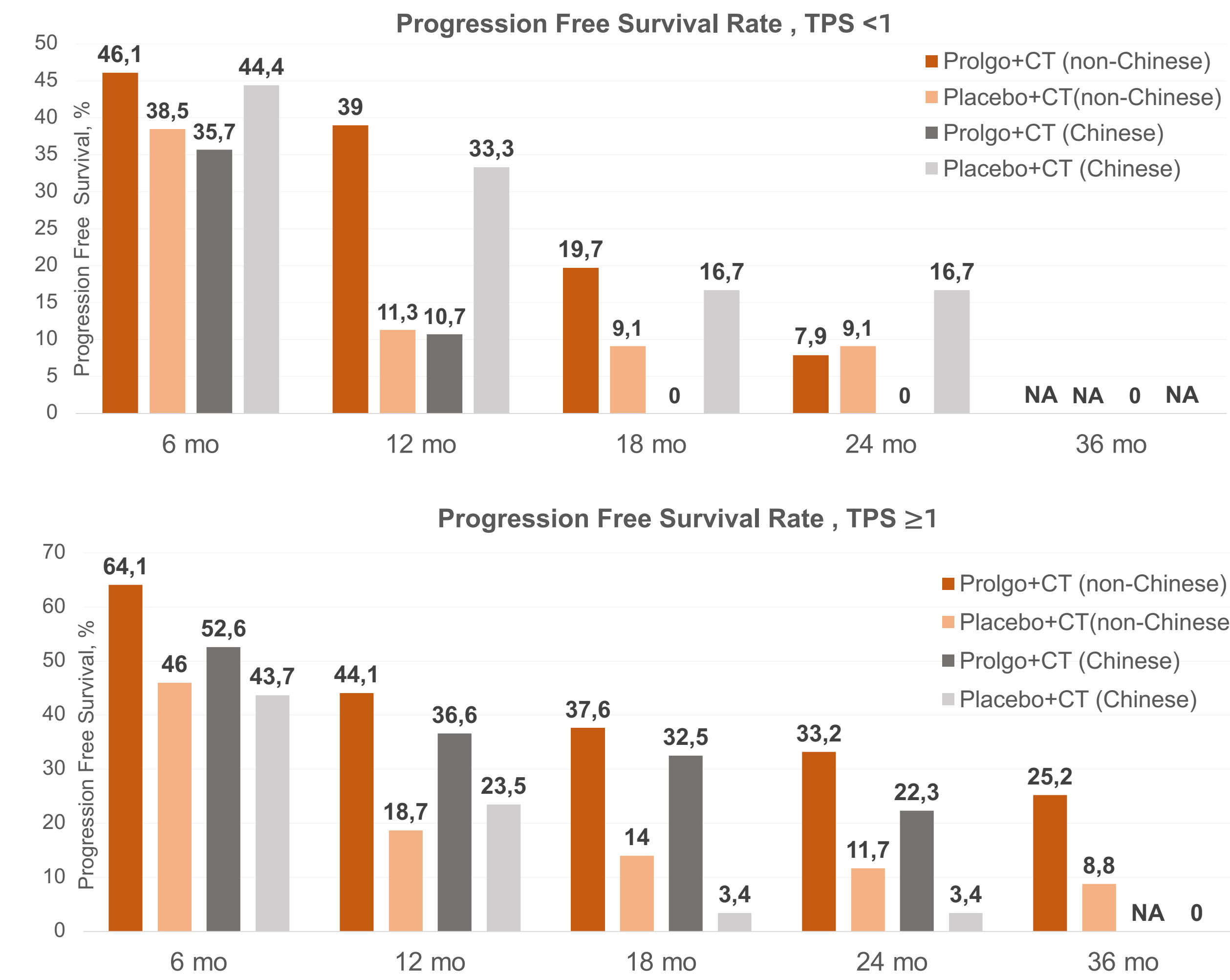


Figure 6. Progression Free Survival per RECIST 1.1. Subgroup analysis by race and level of PD-L1 expression at baseline (TPS < 1%, TPS ≥1%). Full Analysis Set



CONCLUSION:

The DOMAJOR data continue to demonstrate that adding prolgolimab to pemetrexed and platinum-based chemotherapy provides a clinically meaningful benefit, with a favorable safety profile, in patients with previously untreated nonsquamous NSCLC without EGFR or ALK alterations. The confirmed OS benefit reinforces the primacy of OS over PFS in the final assessment of efficacy. However, the magnitude of PFSbenefit in patients with PD-L1–negative tumors remains uncertain. In addition, subgroup findings suggest potentially different patterns of immunotherapy efficacy between Asian and non-Asian patients; these exploratory observations should be interpreted cautiously and require further investigation.

REFERENCES:

1. Tjulandin, S. et al. Novel PD-1 inhibitor prolgolimab: Expanding non-resectable/metastatic melanoma therapy choice. Eur. J. Cancer. 149, 222–232 (2021).
2.Laktionov K, Smolin A, Stroyakovskiy D, Moiseenko V, Dvorkin M, Andabekov T, et al. Prolgolimab with chemotherapy as first-line treatment for advanced non-squamous non-small-cell lung cancer. Eur J Cancer. 2025;217:115255.



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