

# Preliminary results from a phase II trial evaluating the safety and efficacy of JS207, a bispecific antibody targeting PD-1 and VEGF, in combination with chemotherapy in patients with metastatic colorectal cancer

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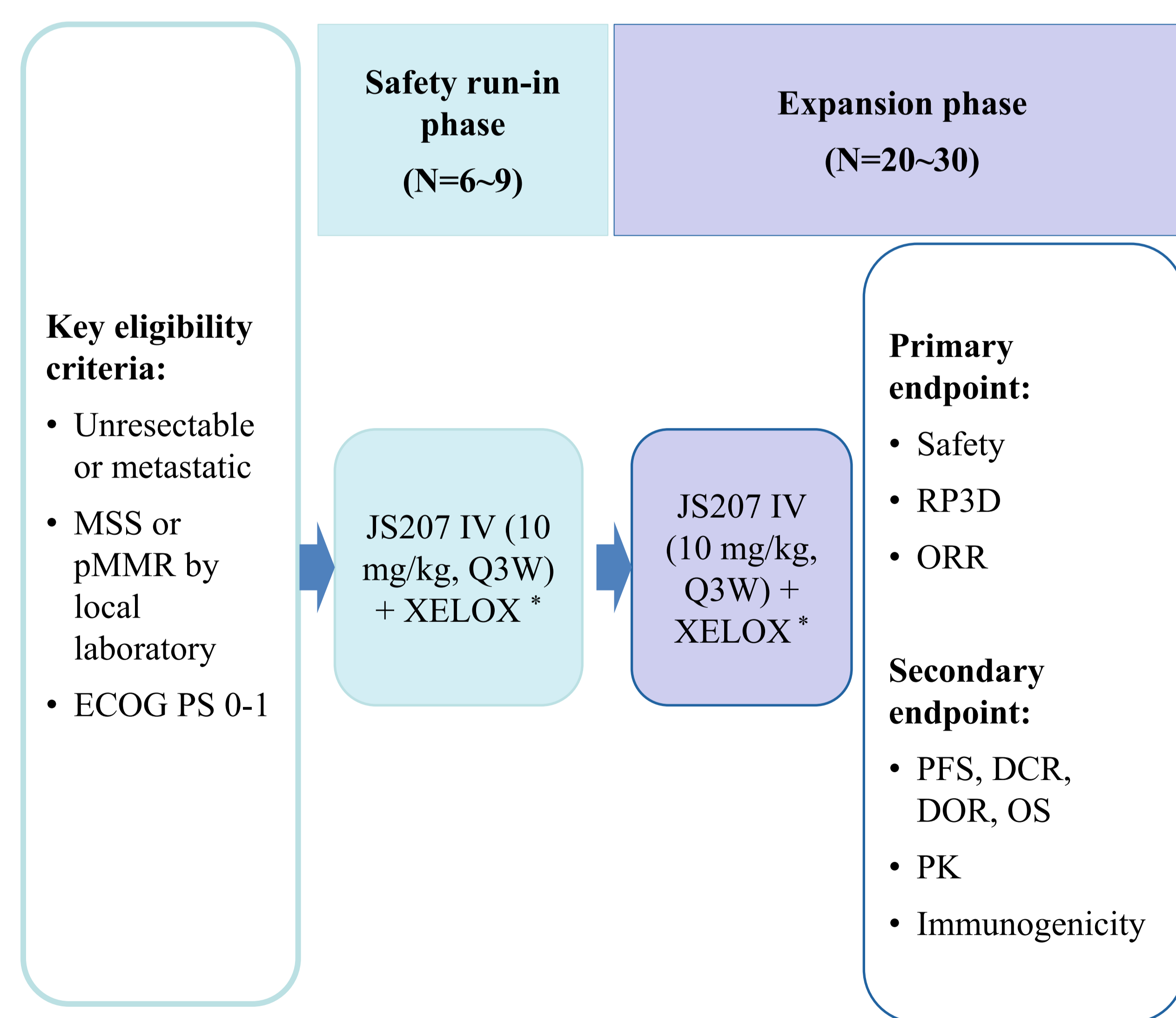
## INTRODUCTION

- JS207 is a bispecific IgG4 antibody targeting programmed death receptor 1 and vascular endothelial growth factor A.
- This Phase II study (NCT06885385) evaluated the preliminary safety and efficacy of JS207 in combination with XELOX (capecitabine + oxaliplatin) as first-line therapy for metastatic colorectal cancer (mCRC).

## STUDY DESIGN

- Patients with mCRC who had not received prior systemic antitumor therapy for metastatic disease, or recurred/progressed at least 12 months after last neoadjuvant/adjuvant therapy were eligible for the study.
- In the initial safety run-in phase, 6 to 9 patients were enrolled to evaluate the safety and tolerability of JS207 (10 mg/kg, every 3 weeks) in combination with XELOX.
- Patients received treatment until progression or unacceptable toxicity, with JS207 continued for up to 2 years and oxaliplatin capped at 6–8 cycles, patients then transitioned to capecitabine maintenance therapy.
- Once acceptable safety has been confirmed, the study will enter the expansion phase.

Figure 1. Study Design



\* XELOX: oxaliplatin 130 mg/m<sup>2</sup> day 1 every cycle; capecitabine 1000 mg/m<sup>2</sup> twice daily days 1-14.

MSS, Microsatellite Stable; pMMR, proficient Mismatch Repair; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; RP3D, Recommended Phase 3 Dose; Q3W, once every 3 weeks; ORR, Objective Response Rate; PFS, Progression-Free Survival; DCR, Disease Control Rate; DOR, Duration of Response; OS, Overall Survival; PK, pharmacokinetics.

## RESULTS

### Baseline characteristics

- As of January 13, 2026, 32 patients were enrolled and received JS207 in combination with XELOX, including 9 in the safety run-in phase and 23 in the dose-expansion phase. The median age was 61 years, with 56% of the patients with primary tumors located in the left sided colon and 44% in the right sided colon. At baseline, 53% of patients had liver metastases, while 50% had lung metastases (Table 1).

Table 1. Baseline characteristics

	Total, N=32
<b>Age</b>	
Median (Min-Max)	61.0 (36-74)
<b>Gender, n (%)</b>	
Female	12 (37.5)
Male	20 (62.5)
<b>ECOG PS=1, n (%)</b>	26 (81.3)
<b>Clinical Stage at Screening (AJCC 8th), n (%)</b>	
IV A	14 (43.8)
IV B	14 (43.8)
IV C	4 (12.5)
<b>Primary Tumor Site<sup>a</sup>, n (%)</b>	
Left Colon/Rectum	18 (56.3)
Right Colon	14 (43.8)
<b>Liver Metastasis, n (%)</b>	17 (53.1)
<b>Lung Metastasis, n (%)</b>	16 (50.0)
<b>RAS Mutation Status<sup>b</sup>, n (%)</b>	
Wild Type	3 (9.4)
Mutated	14 (43.8)
Unknow	15 (46.9)
<b>BRAF Mutation Status, n (%)</b>	
Wild Type	8 (25.0)
Mutated	1 (3.1)
Unknow	23 (71.9)
<b>MSS/pMMR, n (%)</b>	32 (100)

<sup>a</sup> Primary tumor site: Right colon: ileocecum, ascending colon, and transverse colon; left colon: descending colon and sigmoid colon.

<sup>b</sup> RAS/BRAF testing was not mandatory at baseline.

### Safety

- By the cutoff date, the median treatment duration was 4.63 (range: 0.49-7.75) months.
- No dose-limiting toxicity was observed in safety run-in phase. Treatment-related adverse events (TRAEs) were reported by 96.9% of patients, with 40.6% of grade  $\geq 3$  TRAEs. Treatment-related serious adverse events (SAEs) were observed in 9 (28.1%) patients, and immune-related adverse events (irAEs) occurred in 7 (21.9%) patients. No fatal TRAEs were observed.
- The summary of safety data is presented in Table 2, and the most common TRAEs are listed in Table 3.

Table 2. Summary of safety

	Total, N=32, n (%)
<b>TRAE</b>	31 (96.9)
Grade $\geq 3$ TRAE	13 (40.6)
<b>irAE</b>	7 (21.9)
Grade $\geq 3$ irAE	1 (3.1)
<b>SAE</b>	13 (40.6)
Treatment Related	9 (28.1)
<b>TRAE Leading to Drug Reduction</b>	3 (9.4)
<b>TRAE Leading to Drug Discontinuation</b>	1 (3.1)
<b>TRAE Leading to Death</b>	0

TRAE was defined as an event with a suspected relationship to either JS207 or any chemotherapeutic agent in the regimen, as assessed by the investigator.

Table 3. Most common TRAEs (total incidence  $\geq 20\%$ )

	Total, N=32, n (%)
Anemia	16 (50.0)
Neutrophil count decreased	15 (46.9)
Platelet count decreased	15 (46.9)
White blood cell count decreased	12 (37.5)
Blood lactate dehydrogenase increased	11 (34.4)
Decreased appetite	9 (28.1)
Vomiting	9 (28.1)
Aspartate aminotransferase increased	8 (25.0)
Hypoalbuminemia	8 (25.0)
Alpha hydroxybutyrate dehydrogenase increased	7 (21.9)
Hypoesthesia	7 (21.9)
Lipase increased	7 (21.9)
Proteinuria	7 (21.9)

### Efficacy

- The median follow-up was 5.06 (range: 0.82-8.57) months.
- Among 31 patients who underwent at least one post-baseline tumor assessment, 22 achieved a partial response and 8 achieved stable disease. The ORR was 71.0% and the DCR was 96.8% (Table 4).
- At the time of this analysis, the median PFS and median DOR had not been reached, with 26 patients remaining on treatment.
- Among responders, the longest duration of response remained ongoing at 8 months.

Table 4. Best overall response

	JS207+XELOX, N=31*
<b>ORR, n (%)</b>	22 (71.0)
95% CI	52.0, 85.8
<b>DCR, n (%)</b>	30 (96.8)
95% CI	83.3, 99.9

\* One patient had no post-baseline tumor assessment.

Figure 2. Percent Change from Baseline

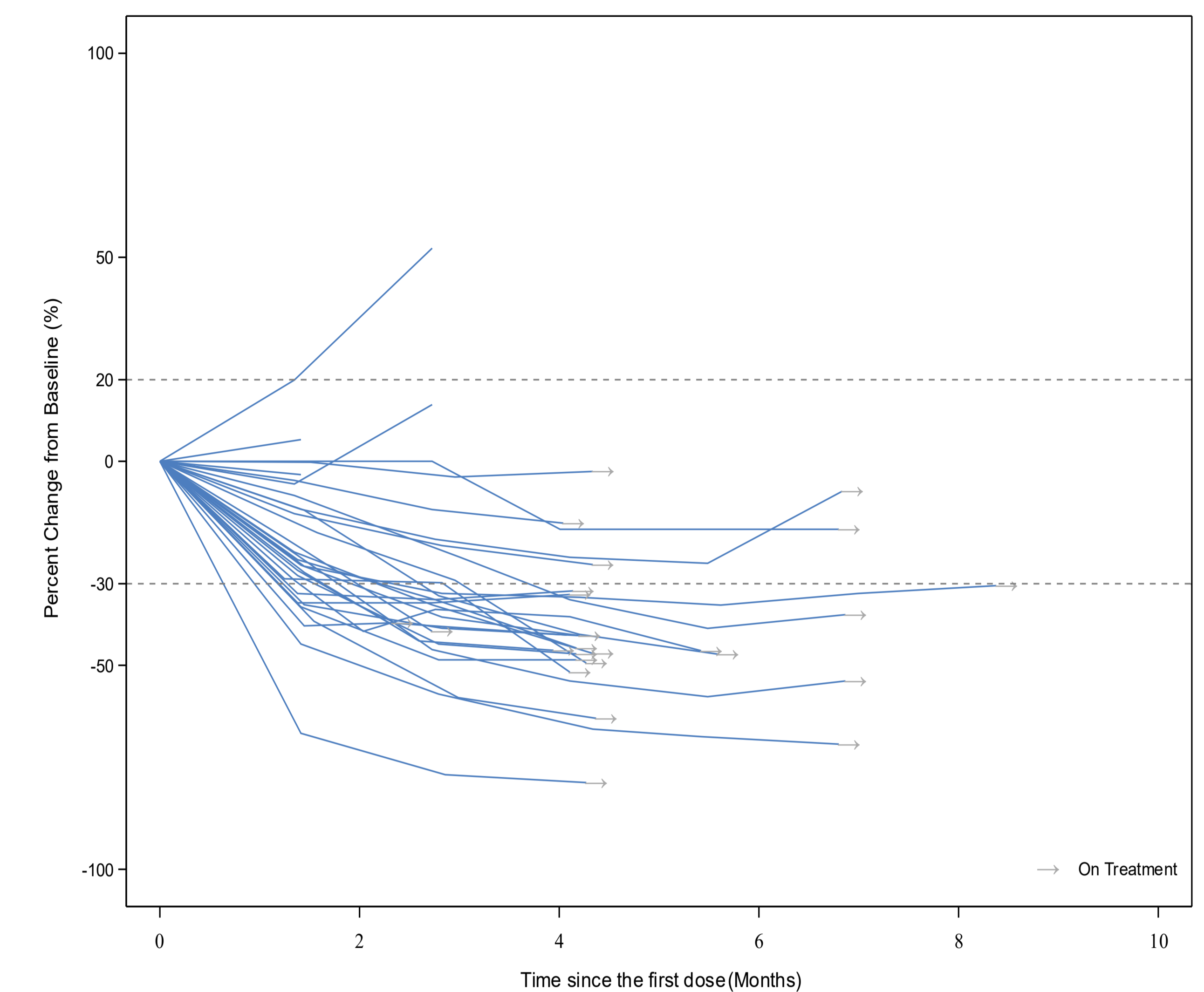
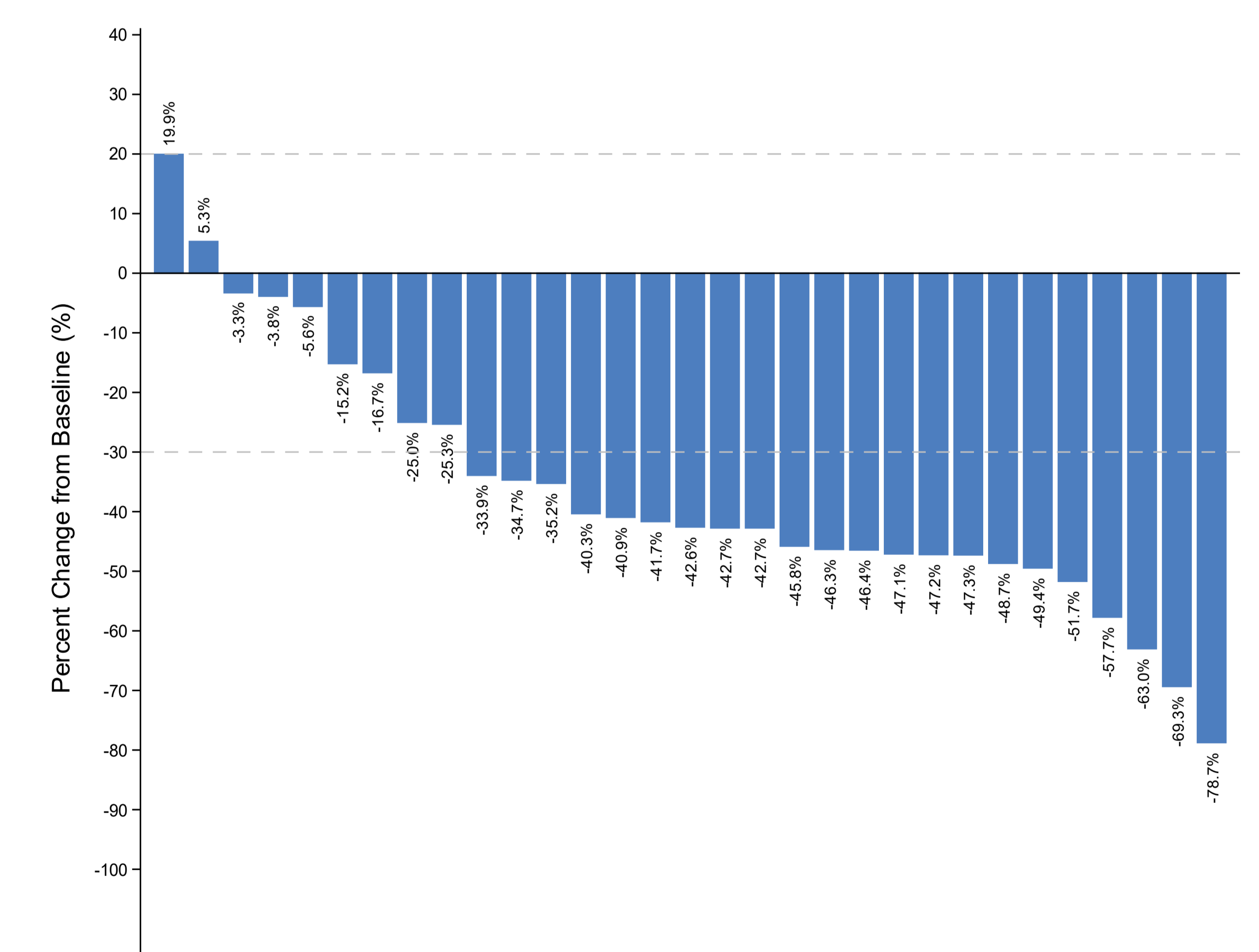


Figure 3. Best Percent Change from Baseline



## CONCLUSION

- JS207 in combination with XELOX as first-line treatment for mCRC patients was well tolerated with promising efficacy.**

- Median PFS and DOR were not reached.**

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