
ANNUAL MEETING
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Efficacy and safety of serplulimab (an anti-PD-1 antibody) combined with albumin-bound paclitaxel in patients with advanced cervical cancer who have progressive disease or intolerable toxicity after first-line standard chemotherapy

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Unlabeled/Investigational Uses

I will not be discussing any unlabeled or investigational uses of any pharmaceutical products or medical devices.

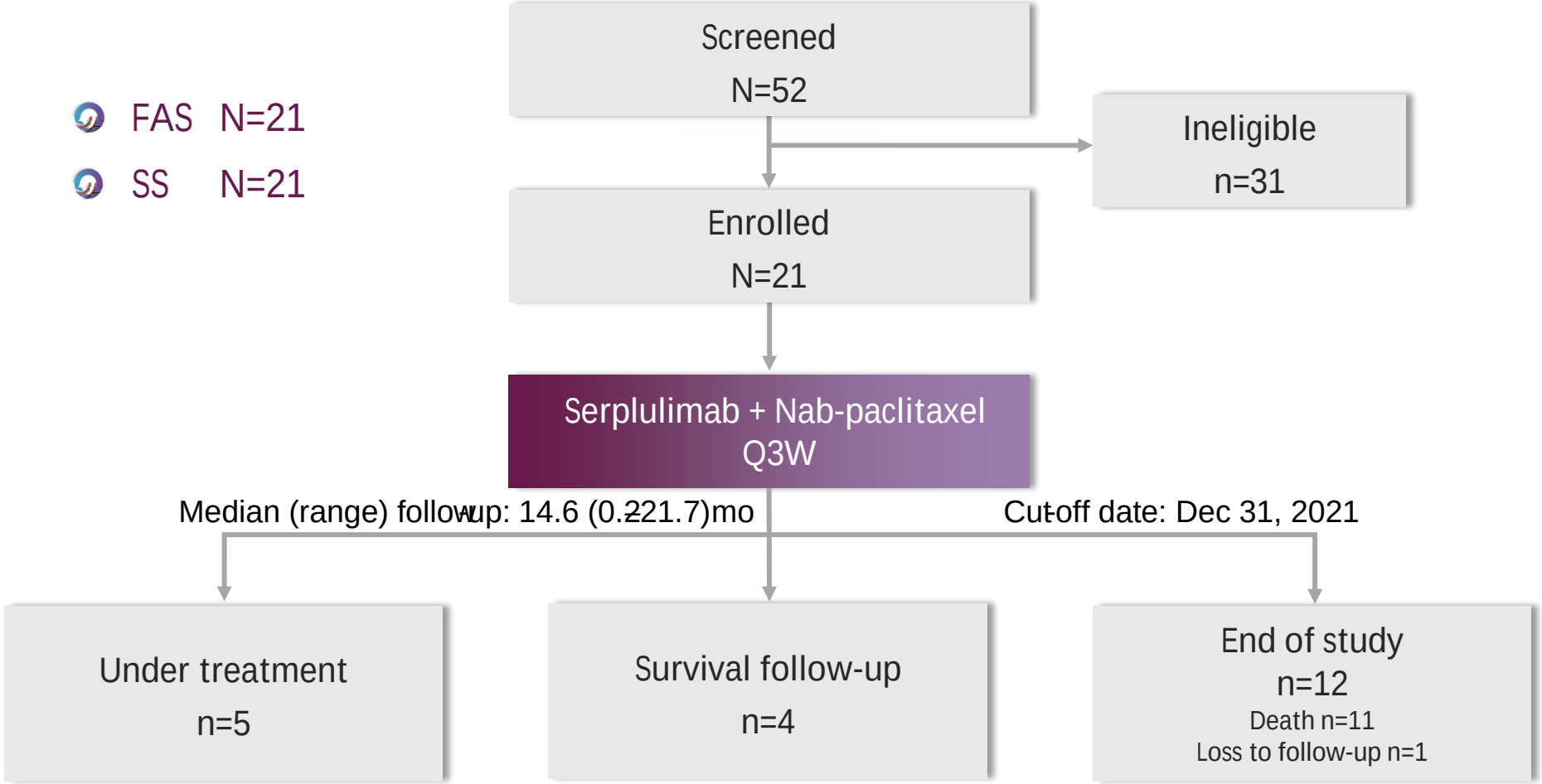
Background

Study design

CPS, combined positive score; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IRRC, independent radiological review committee; IV, intravenous infusion; ORR, overall response rate; OS, overall survival; PD-L1, programmed death ligand-1; PFS, progression-free survival; Q12W, every 12 weeks; Q3W, every 3 weeks; RECIST, response evaluation criteria in solid tumors;

Patient distribution

- FAS N=21
- SS N=21



FAS, full analysis set; SS, safety set;

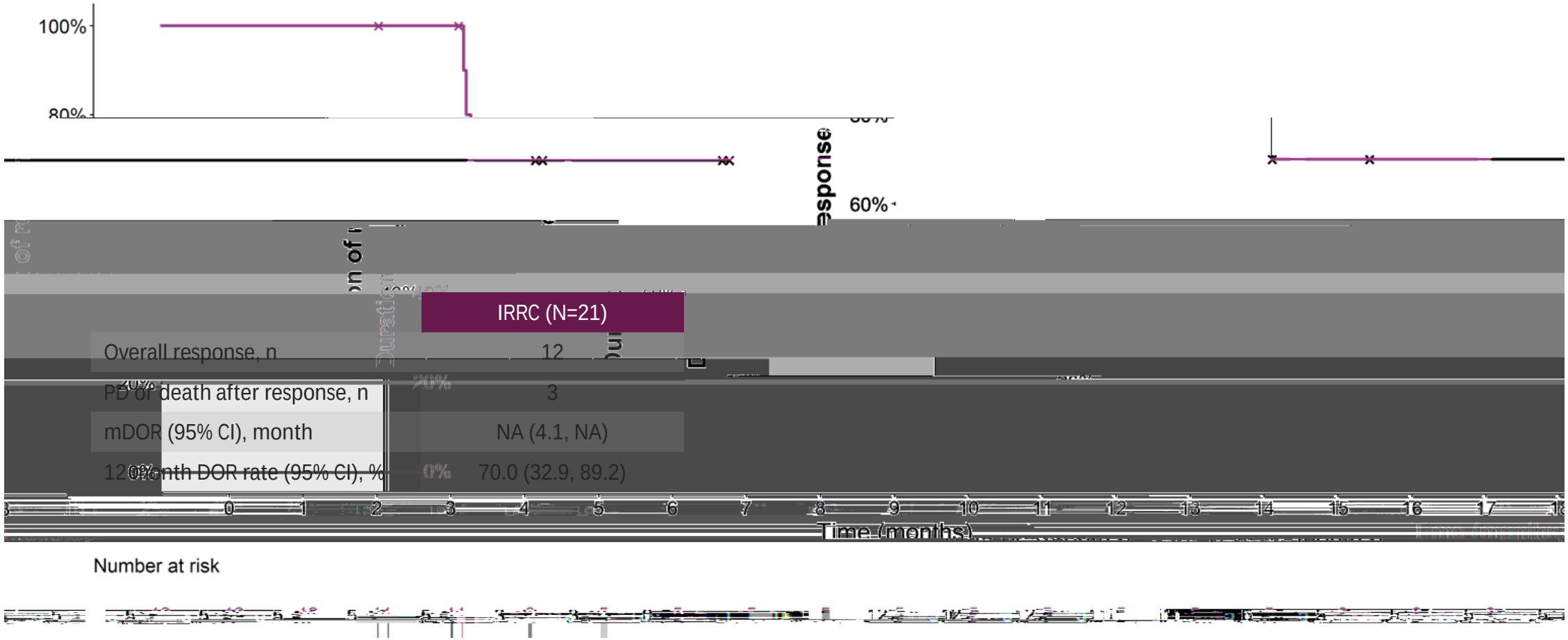


Objective response rate (ORR)

	IRRC (N=21)
ORR, n (%) [95% CI]	12 (57.1) [34.0, 78.2]
DCR, n (%)	

CI, confidence interval; CR, complete response; DCR, disease control rate; FAS, full analysis set; IRRC, independent radiological review committee; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease

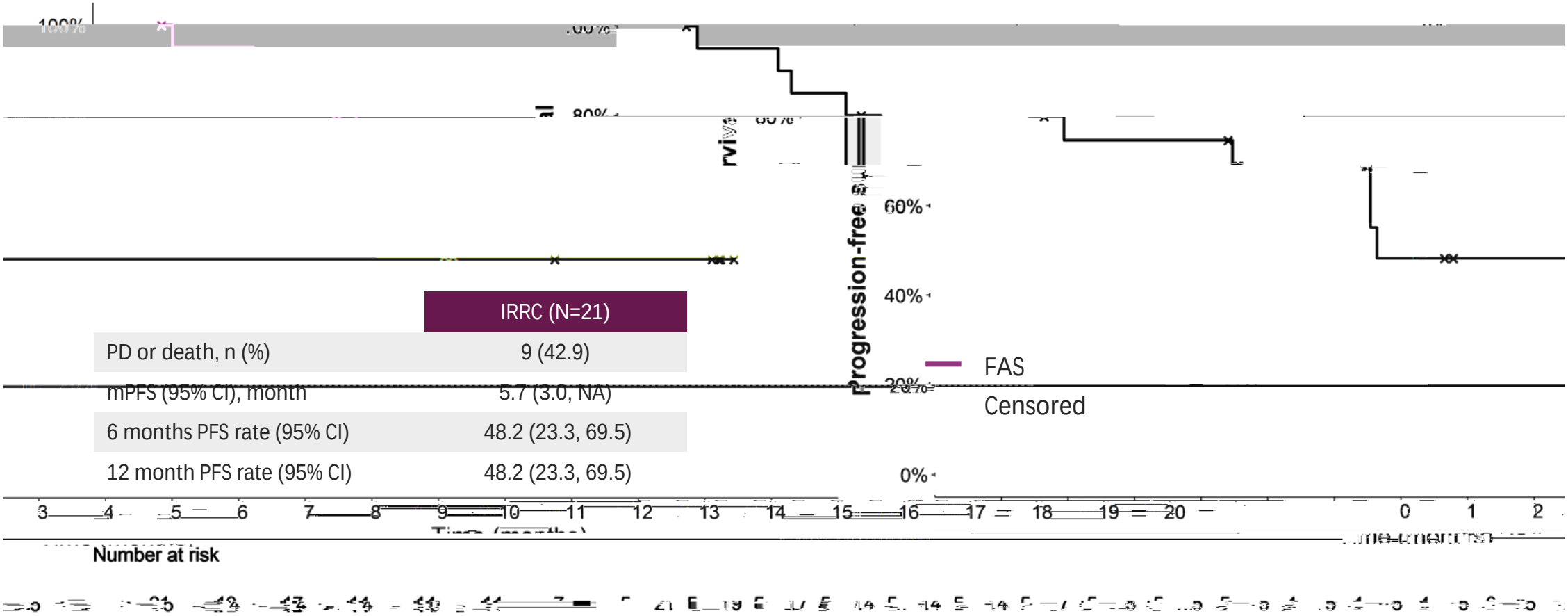
Duration of response (DOR)



	IRRC (N=21)
Overall response, n	12
PD or death after response, n	3
mDOR (95% CI), month	NA (4.1, NA)
12-month DOR rate (95% CI), %	70.0 (32.9, 89.2)

CI, confidence interval; mDOR, median duration of response; FAS, full analysis set; IRRC, independent radiological review committee; NA, not available; PD, progressive disease;

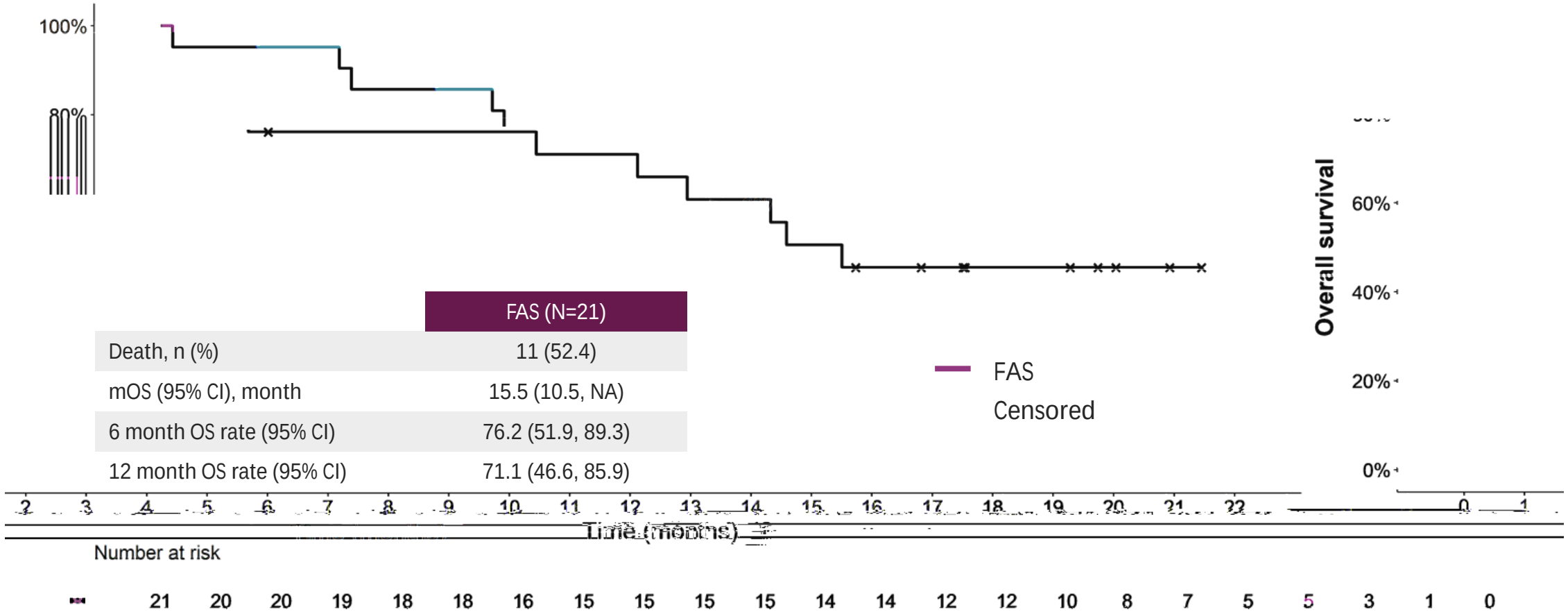
Progression-free survival (PFS)



	IRRC (N=21)
PD or death, n (%)	9 (42.9)
mPFS (95% CI), month	5.7 (3.0, NA)
6 months PFS rate (95% CI)	48.2 (23.3, 69.5)
12 month PFS rate (95% CI)	48.2 (23.3, 69.5)

CI, confidence interval; FAS, full analysis set; IRRC, independent radiological review committee; NA, not available; PD, progressive disease; mPFS, median progression-free survival;

Overall survival (OS)



	FAS (N=21)
Death, n (%)	11 (52.4)
mOS (95% CI), month	15.5 (10.5, NA)
6 month OS rate (95% CI)	76.2 (51.9, 89.3)
12 month OS rate (95% CI)	71.1 (46.6, 85.9)

CI, confidence interval; FAS, full analysis set; IRRC, independent radiological review committee; NA, not available; mOS, median overall survival;

Adverse events summary

	SS (N=21)
TEAE, n (%)	21 (100)
CTCAE grade ≥3 TEAE	17 (81.0)
ADR	19 (90.5)
CTCAE grade ≥3 ADR	7 (33.3)
SAE	8 (38.1)
TEAE leading to serplulimab discontinuation	0
AESI	12 (57.1)
IRR	0
irAE	12 (57.1)
CTCAE grade ≥3 irAE	2 (9.5)

ADR, adverse drug reaction; AESI, adverse event of special interest; CTCAE, Common Terminology Criteria for Adverse Events; irAE, immune-related adverse event; IRR, infusion related reaction; SAE, serious adverse event; TEAE, treatment-emergent adverse event; SS, safety set;

Most common TEAEs and irAEs

Preferred Term (PT)	SS (N=21)	
TEAE, n (%)	Incidence >20%	CTCAE grade ≥3
Anaemia	16 (76.2)	5 (23.8)

CTCAE, Common Terminology Criteria for Adverse Events; irAE, immune-related adverse event; TEAE, treatment-emergent adverse event; SS, safety set;

Conclusions

- Serplulimab and nab-paclitaxel combination therapy showed more excellent anti-tumor activity in patients with advanced cervical cancer who failed first-line standard chemotherapy than PD-1 or nab-paclitaxel monotherapy;
  - ✓ ORR assessed by IRRC was 57.1%
  - ✓ mDOR was not reached, 12 month DOR rate assessed by IRRC was 70.0%
  - ✓ mPFS assessed by IRRC was 5.7 (95% CI: 3.0, NA) months
  - ✓ mOS was 15.5 (95% CI: 10.5, NA) months, 12 month OS rate was 71.1%
- Meanwhile, Serplulimab in combination with nab-paclitaxel showed a manageable safety profile.
  - ✓ No grade 4–5 irAE occurred, and the incidence of grade 3 irAE was 9.5%

CI, confidence interval; CTCAE, Common Terminology Criteria for Adverse Events; mDOR, median duration of response; irAE, immune-related adverse event; IRRC, independent radiological review committee; NA, not available; ORR, objective response rate; mOS, median overall survival; mPFS, median progression-free survival;

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