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The Nivolumab as maintenance therapy following platinum-based chemotherapy in EGFR-mutant lung cancer patients after tyrosine kinase inhibitor failure

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Background

- Treatment outcomes for lung cancer have improved with targeted therapy.

- In EGFR-mutant NSCLC, EGFR-TKI have exhibited advantages.

  However, with EGFR-TKI, resistance can be acquired.

- In recent years, immunotherapy has become integrated into the treatment plan of NSCLC.

Background

- Previous studies reported that outcome of immunotherapy can be improved when combined with cytotoxic chemotherapy or radiotherapy.

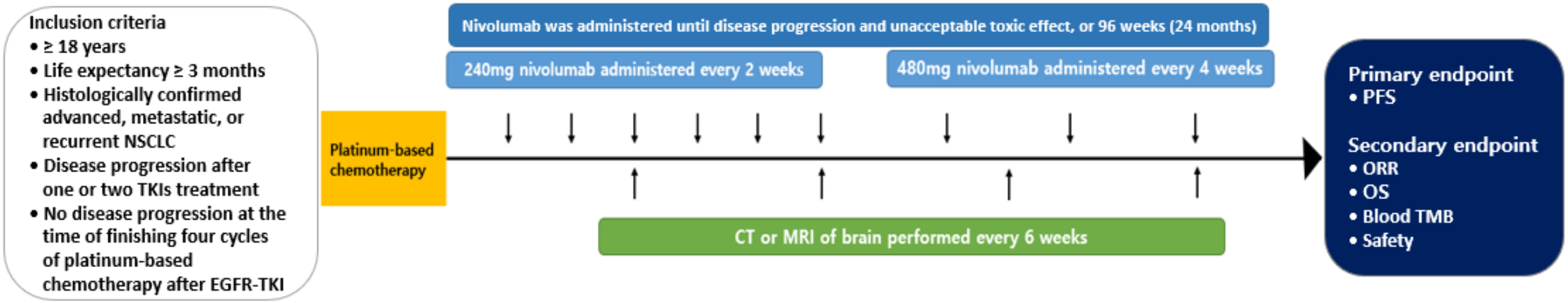
- **Aim of this study**

  ① Efficacy of nivolumab maintenance following platinum-based chemotherapy in EGFR-mutant NSCLC patients with disease progression after EGFR-TKI

  ② In addition, the role of tumor mutation burden (TMB) in circulating tumor DNA on treatment outcomes

Method

- Prospective, open label, single arm phase 2 trial



Baseline characteristics

	All patients (N = 26)
Median age (range)	61.0 (55.0–66.3)
Male, n(%)	9 (34.6)
Ever smoker, n(%)	9 (34.6)
Tumor type, n(%)	
Adenocarcinoma	26 (100.0)
Primary EGFR mutation, n(%)	
19del	18 (69.2)
L959R	5 (19.2)
Others	3 (11.5)
PD-L1, n(%)	
< 1%	7 (26.9)
1 – 49%	10 (38.5)
50% <	1 (3.8)
TMB, n(%)	
< 10mt/Mb	24 (92.3)
10mt/Mb <	2 (7.7)

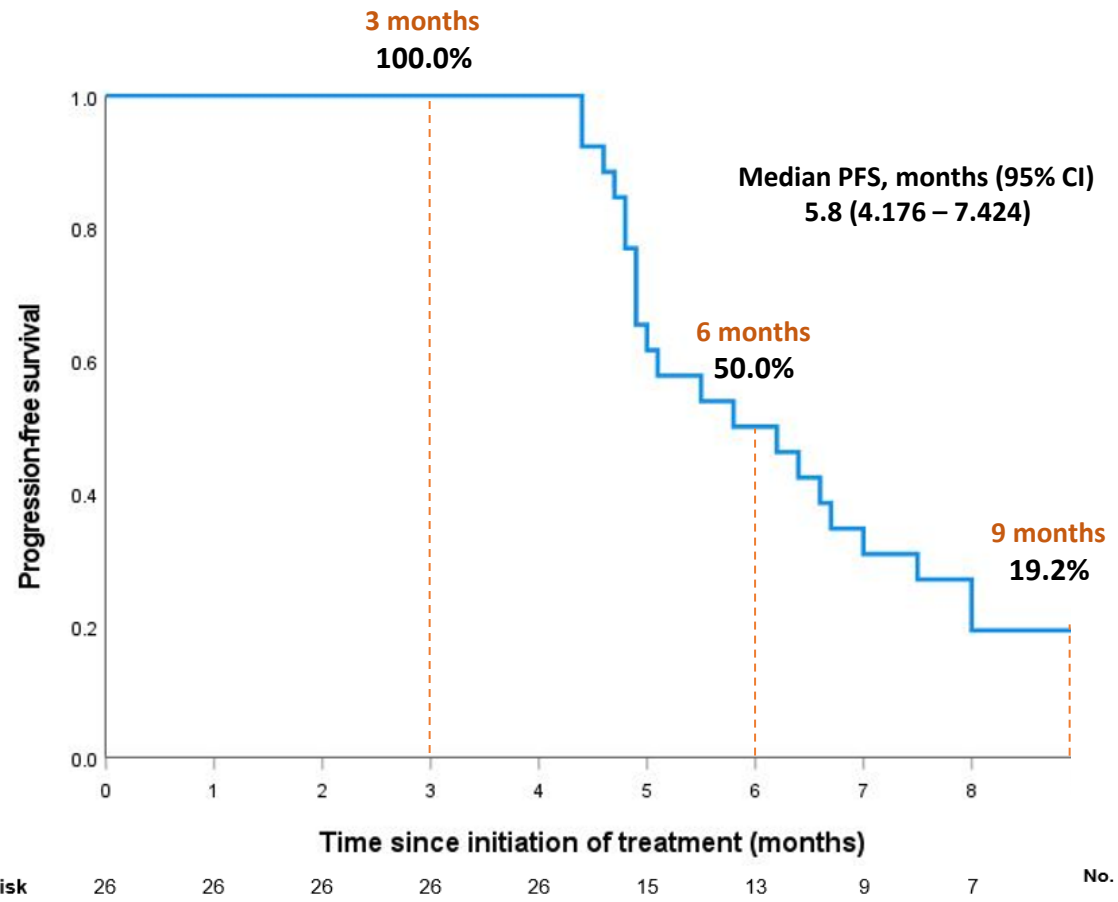
Baseline characteristics

	All patients (N = 26)
Initial disease status	
I	1 (3.8)
III	1 (3.8)
IV	24 (92.3)
Metastasis, n (%)	
Single	14 (53.8)
Multiple	12 (46.2)
Prior treatment, n (%)	
Surgery	1 (3.8)
CCRT	1 (3.8)
Radiotherapy	7 (26.9)
Chemotherapy	
1st line EGFR-TKI	
Afatinib	6 (23.1)
Geftinib	20 (76.9)
2nd line EGFR-TKI	
Osimeritinib	12 (46.2)
Salvage chemotherapeutic agents Before nivolumab maintenance, n (%)	
Carboplatin + Gemcitabine	19 (73.1)
Cisplatin + Gemcitabine	7 (26.9)

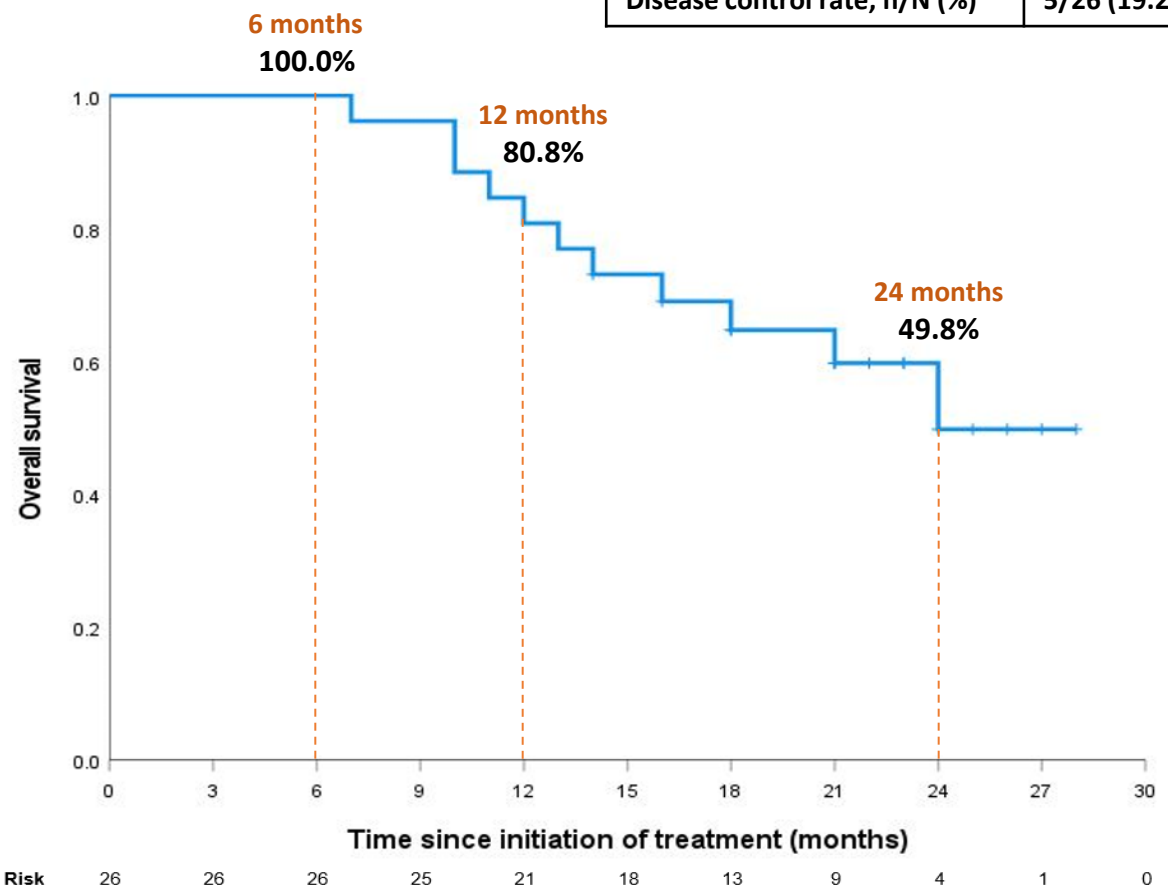
Overall efficacy of nivolumab maintenance therapy following platinum-based chemotherapy

	N = 26
Overall response rate, n/N (%)	2/26 (7.7)
Disease control rate, n/N (%)	5/26 (19.2)

A. Progression-free survival



B. Overall survival



Comparison of baseline characteristics between the patients in nivolumab maintenance therapy

	Responder group (n =5)	Non-responder (n = 21)	*p* value
Median age (range)	61.0 (57.0 – 68.0)	61.0 (54.0 – 66.5)	0.885
Male, n(%)	1 (20.0)	8 (38.1)	0.628
Ever-smoker, n(%)	1 (20.0)	8 (38.1)	0.628
Prior chemotherapy			
1st line EGFR-TKI			0.298
Afatinib	0 (0.0)	6 (28.6)	
Geftinib	5 (100.0)	15 (71.4)	
2nd line EGFR-TKI			0.635
Osimeritinib	3 (60.0)	9 (42.9)	
Salvage chemotherapeutic agents before nivolumab maintenance			0.588
Carboplatin + Gemcitabine	3 (60.0)	16 (76.2)	
Cisplatin + Gemcitabine	2 (40.0)	5 (23.8)	
Primary EGFR mutation, n(%)			0.253
19del	5 (100.0)	13 (61.9)	
L857R	0 (0.0)	5 (23.8)	
Others	0 (0.0)	3 (14.3)	
PD-L1, n(%)			0.914
< 1%	1 (20.0)	6 (28.6)	
1 – 49%	2 (40.0)	8 (38.1)	
50% <	0 (0.0)	1 (4.8)	
TMB, n(%)			> 0.999
< 10mt/Mb	5 (100.0)	19 (90.5)	
10mt/Mb <	0 (0.0)	2 (9.5)	

Treatment-related adverse events of nivolumab maintenance therapy

	Any grade, n(%)	3-4 Grade, n(%)	Serious AE, n(%)
Laboratory abnormalities			
Hemoglobin	1 (3.8)	1 (3.8)	0 (0.0)
Glucose	1 (3.8)	1 (3.8)	1 (3.8)
Total cholesterol	1 (3.8)	0 (0.0)	0 (0.0)
Aspartate aminotransferase	5 (19.2)	1 (3.8)	0 (0.0)
Alanine aminotransferase	4 (15.4)	2 (7.7)	0 (0.0)
Alkaline phosphatase	2 (7.7)	0 (0.0)	0 (0.0)
γ-glutamyl transferase	1 (3.8)	0 (0.0)	0 (0.0)
Lactate dehydrogenase	1 (3.8)	0 (0.0)	0 (0.0)
Other adverse events			
Nausea	3 (11.5)	0 (0.0)	0 (0.0)
Myalgia	2 (7.7)	0 (0.0)	0 (0.0)
Dyspnea	1 (3.8)	0 (0.0)	0 (0.0)
Rash	2 (7.7)	0 (0.0)	0 (0.0)
Thyroid dysfunction	2 (7.7)	0 (0.0)	0 (0.0)
Polymyositis	1 (3.8)	1 (3.8)	1 (3.8)
Ocular myasthenia gravis	1 (3.8)	1 (3.8)	1 (3.8)
Macular edema	1 (3.8)	0 (0.0)	0 (0.0)

Conclusion

- Nivolumab maintenance following platinum-based chemotherapy did not show clinical benefits after EGFR-TKI failure in patients with EGFR-mutant NSCLC