Interim data on first-line nivolumab plus ipilimumab with 2 cycles of platinum-based chemotherapy in patients with metastatic non-small cell lung cancer from the German non-interventional study FINN

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Introduction

- The dual immunotherapy combination of nivolumab (NIVO) and ipilimumab (IPI), immune-checkpoint inhibitors with distinct but complementary mechanisms of action,[1,2] has demonstrated long-term, durable survival benefit in several metastatic solid tumor types,[3,4] including metastatic non-small cell lung cancer (NSCLC)[5,6]
- In the randomized, phase 3 CheckMate 9LA study (NCT03215706), first-line (1L) NIVO + IPI with 2 cycles of platinum-doublet chemotherapy (chemo) vs chemo alone (4 cycles) showed significant improvement in overall survival (OS), along with a manageable safety profile, in patients with metastatic NSCLC[7]
  - At the final 6-year follow-up, NIVO + IPI + chemo continued to show long-term, durable OS benefit vs chemo alone, regardless of tumor programmed death ligand 1 (PD-L1) expression or histology[5]
  - This regimen is approved in the United States, European Union, and several other countries as 1L treatment for adult patients with metastatic NSCLC with no *EGFR*/*ALK* alterations, regardless of tumor PD-L1 expression or histology[8,9]
- However, real-world data on 1L NIVO + IPI + chemo in patients with metastatic NSCLC are limited

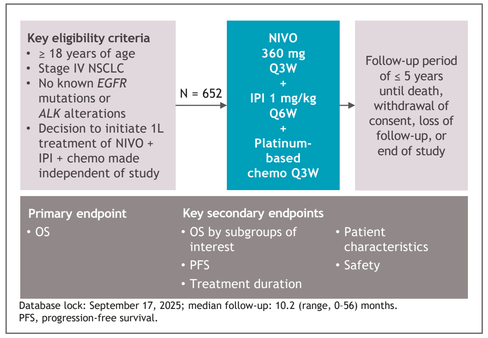
Objectives

- The non-interventional study (NIS) FINN (NCT04794010) aims to evaluate real-world data on 1L NIVO + IPI + chemo in the post-market authorization approval period in Germany[10]
- Previous interim data (Nov 7, 2024) from 489 patients were reported[11]
- In this analysis, we report baseline characteristics, updated OS, and safety outcomes in 600 patients (date of data cut-off: Sep 17, 2025), with a median follow-up of 10.2 (range, 0–56) months

Methods

- The study design for the FINN study is shown in **Figure 1**
- Enrollment for this prospective, observational study is complete, with 652 patients from 90 sites enrolled in Germany
- Assessments are conducted per routine local clinical practice
- All data analyses are of a descriptive nature and no formal hypotheses will be tested

Figure 1. FINN study design



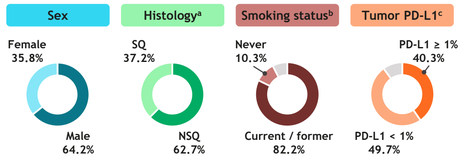
Database lock: September 17, 2025; median follow-up: 10.2 (range, 0–56) months.
PFS, progression-free survival.

Results

Patient characteristics

- This analysis included a total of 600 patients who met eligibility criteria and received ≥1 dose of 1L NIVO + IPI + chemo
  - Of those, 151 (25.2%) are still on study
- Baseline demographic and clinical characteristics in the overall population are shown in **Figure 2** and **Table 1**
  - Median age was 67 (range, 39–86) years
  - The median number of distant metastases was 2.0 (range, 0–12)
  - Most patients (69.2%) had stage M1b/M1c (extrathoracic metastasis), with metastasis observed in bone (30.8%), brain (20.8%), and liver (15.8%)
- The proportion of patients with at least 1 comorbidity was 88.7%

Figure 2. Key baseline characteristics in the overall population (N = 600)



Data are shown as percentages of the overall population (N = 600).
[a]Missing: 0.2%.[b]Missing/unknown: 7.5%. [c]Missing/unknown: 10.0%.
NSQ, non-squamous; SQ, squamous.

Table 1. Summary of baseline characteristics

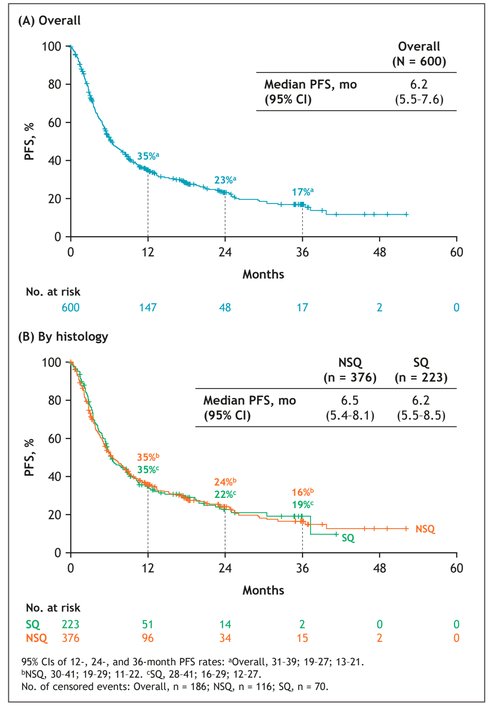
Characteristic	Overall (N = 600)
Age, median (range), y	67.0 (39.0-86.0)
Age group, %	
< 66 y / 66-75 y / > 75 y	43.2 / 42.3 / 14.5
ECOG PS, %	
0 / 1	28.0 / 57.2
2 / ≥ 3	10.7 / 1.8
Missing	2.3
Tumor stage (T), %	
T1a / T1b	3.5 / 5.8
T2a / T2b	8.2 / 6.2
T3 / T4	18.5 / 43.7
Tx / missing	13.2 / 1.0
Regional lymph node stage (N), %	
N0 / N1 / N2	15.0 / 10.7 / 31.5
N3 / Nx / missing	29.2 / 13.5 / 0.2
No. of distant metastases, median (range)	2 (0-12)
Metastasis stage (M), %	
M1a	30.2
M1b[a] / M1c (extrathoracic metastasis)	21.8 / 47.3
Metastasis site,[b] %	
Lung (contralateral)	33.0
Bone	30.8
Lymph nodes (extrathoracic)	24.0
Brain	20.8
Pleural effusion (malignant)	19.7
Liver	15.8
Adrenal gland	15.5
Soft tissue / skin	5.8
Other	11.3

Percentages may not sum to 100 due to rounding.
[a]M1b, n = 69; M1b2a, n = 24; M1b2b, n = 21; unknown, n = 17. [b]Multiple sites are possible.
PS, performance status; y, years.

PFS

- Median (95% CI) PFS was 6.2 (5.5-7.6) months; 36-month PFS rate was 17% (**Figure 3A**)
- Median (95% CI) PFS was 6.5 (5.4-8.1) months and 6.2 (5.5-8.5) months in patients with NSQ and SQ histology, respectively (**Figure 3B**)

Figure 3. PFS (overall and by histology)



95% CIs of 12-, 24-, and 36-month PFS rates: [a]Overall, 31-39; 19-27; 13-21.
[b]NSQ, 30-41; 19-29; 11-22. [c]SQ, 28-41; 16-29; 12-27.
No. of censored events: Overall, n = 186; NSQ, n = 116; SQ, n = 70.

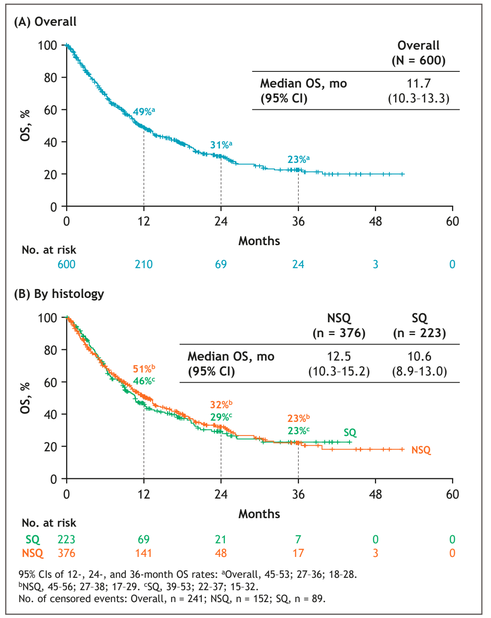
OS

- At a median follow-up of 10.2 months, median (95% CI) OS was 11.7 (10.3-13.3) months; 36-month OS rate was 23% (**Figure 4A**)
- Median (95% CI) OS was 12.5 (10.3-15.2) months and 10.6 (8.9-13.0) months in patients with NSQ and SQ histology, respectively (**Figure 4B**)
- OS by key patient subgroups is shown in **Table 2**

Safety

- The median duration of NIVO + IPI treatment was 4.1 (range, 0.1-53.2) months
- At this interim analysis, patients treated with NIVO + IPI + chemo had a manageable safety profile with a total of 397 (66.2%) patients experiencing ≥ 1 adverse event (AE) (**Table 3**)
  - 139 (23.2%) patients experienced ≥ 1 treatment-related serious AE (any grade)

Figure 4. OS (overall and by histology)



95% CIs of 12-, 24-, and 36-month OS rates: [a]Overall, 45-53; 27-36; 18-28.
[b]NSQ, 45-56; 27-38; 17-29. [c]SQ, 39-53; 22-37; 15-32.
No. of censored events: Overall, n = 241; NSQ, n = 152; SQ, n = 89.

Table 2. OS by subgroups

Subgroup	n (%)[a]	Median OS (95% CI), mo	18-month OS rate (SE), %	24-month OS rate (SE), %
Age group, y				
< 66	259 (43.2)	12.5 (10.0-17.6)	42 (3.4)	35 (3.5)
66-75	254 (42.3)	11.1 (10.0-15.2)	39 (3.5)	28 (3.6)
> 75	87 (14.5)	9.0 (6.5-13.3)	31 (6.0)	26 (5.9)
Sex				
Male	385 (64.2)	11.1 (10.0-13.3)	38 (2.8)	29 (2.9)
Female	215 (35.8)	13.0 (9.5-17.4)	41 (3.8)	36 (3.9)
Tumor PD-L1[b]				
< 1%	298 (49.7)	10.7 (9.0-13.0)	36 (3.2)	26 (3.3)
≥ 1%	242 (40.3)	13.0 (10.1-18.0)	44 (3.5)	39 (3.6)
Metastasis stage				
M1b[c]	131 (21.8)	10.6 (6.3-19.3)	40 (6.6)	36 (6.8)
M1c	284 (47.3)	11.0 (9.5-14.0)	37 (3.3)	27 (3.5)
Bone metastasis				
No	415 (69.2)	12.4 (10.7-15.7)	41 (2.7)	32 (2.8)
Yes	185 (30.8)	10.0 (7.8-13.0)	35 (4.0)	28 (4.1)
Brain metastasis				
No	475 (79.2)	11.0 (9.5-13.0)	38 (2.5)	30 (2.6)
Yes	125 (20.8)	15.2 (10.0-21.1)	46 (5.0)	38 (5.3)
Liver metastasis				
No	505 (84.2)	12.4 (10.6-14.4)	40 (2.5)	32 (2.5)
Yes	95 (15.8)	6.9 (5.4-11.1)	35 (5.3)	31 (5.5)

[a]Percentages were calculated using the overall number of patients (N = 600) as the denominator.
[b]Unknown, n = 4; missing, n = 56. [c]M1b, n = 69; M1b2a, n = 24; M1b2b, n = 21; unknown, n = 17.
SE, standard error.

Table 3. Safety summary

AE, n (%)	Overall (N = 600)
Patients with ≥ 1 AE (any / serious / grade 3-4)	397 (66.2) / 157 (26.2) / 155 (25.8)
TRAE[a] (any / grade 3-4)	379 (63.2) / 141 (23.5)
Treatment-related serious AE[a] (any / grade 3-4)	139 (23.2) / 95 (15.8)
Select AE[b] (any / serious / grade 3-4)	121 (20.2) / 54 (9.0) / 42 (7.0)
Other immune-related AE[c] (any / serious / grade 3-4)	29 (4.8) / 11 (1.8) / 10 (1.7)
Other treatment-related AE[d] (any / serious / grade 3-4)	312 (52.0) / 92 (15.3) / 103 (17.2)
Fatal AE related to immunotherapy[e]	1 (0.2)
Fatal AE related to chemo[f]	6 (1.0)

[a]All AEs or serious AEs for which a suspected causal relationship with the treatment exists (at physician's discretion). [b]Included immune-related pneumonitis, colitis, hepatitis, nephritis / renal dysfunction, endocrinopathies, and rash. [c]Included severe infusion reactions, uveitis, pancreatitis, demyelination, Guillain-Barre Syndrome, myasthenic syndrome, encephalitis, and toxic epidermal necrolysis. [d]Other than select/other immune-mediated AEs. [e]Due to liver disorder. [f]Due to neutropenic sepsis (n = 3), sepsis (n = 2), and drug hypersensitivity (n = 1).
TRAE, treatment-related adverse event.

Conclusions

- At interim analysis of the ongoing FINN study, patient characteristics were reflective of those observed in clinical practice
- Effectiveness outcomes with 1L NIVO + IPI + chemo in this analysis are consistent with the results from the CheckMate 9LA study
  - Median (95% CI) PFS was 6.2 (5.5-7.6) months overall with a 36-month PFS rate of 17%; similar results were observed in the NSQ and SQ subgroups
  - Median (95% CI) OS was 11.7 (10.3-13.3) months; the 24-month OS rate was 31%
- Safety results in this analysis are consistent with prior studies of 1L NIVO + IPI + chemo in patients with metastatic NSCLC
- The NIS FINN helps address an unmet need for real-world insights on 1L NIVO + IPI + chemo treatment for metastatic NSCLC and supports the outcomes of the phase 3 CheckMate 9LA study in a population with elderly patients and comorbidities in Germany

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Declaration of interests

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