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# 研究患者

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Eligible adult patients had histologically confirmed squamous-cell or nonsquamous stage IV or recurrent NSCLC, an Eastern Cooperative Oncology Group (ECOG) performance-status score of 0 or 1 (on a 5-point scale, with higher numbers indicating greater disability), and measurable disease according to the Response Evaluation Criteria in Solid Tumors (RECIST), version 1.

# 样本量

RESULTS— Among the 423 patients with a PD-L1 expression level of 5% or more, the median progression-free survival was 4.2 months with nivolumab versus 5.9 months with chemo-therapy (hazard ratio for disease progression or death, 1.15; 95% confidence interval [CI], 0.91 to 1.45; P=0.25), and the median overall survival was 14.4 months versus 13.2 months (hazard ratio for death, 1.02; 95% CI, 0.80 to 1.30).

# 基线特征

The baseline characteristics of all the patients who underwent randomization were similar to those of the patients who were included in the primary efficacy analysis (Table 1, and Tables S2 and S3 in the Supplementary Appendix).

# 试验设计

1. Ettinger DS, Wood DE, Akerley W, et al. NCCN guidelines insights: non-small cell lung cancer, version 4.2016. J Natl Compr Canc Netw 2016;14:255–64. [PubMed: 26957612] 2. Masters GA, Temin S, Azzoli CG, et al. Systemic therapy for stage IV non-small-cell lung cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol 2015;33:3488–515. [PubMed: 26324367] 3. Scagliotti GV, Parikh P, von Pawel J, et al. Phase III study comparing cisplatin plus gemcitabine with cisplatin plus pemetrexed in chemotherapy-naive patients with advanced-stage non-small-cell lung cancer.

# 研究背景

Abstract  
BACKGROUND— Nivolumab has been associated with longer overall survival than docetaxel among patients with previously treated non-small-cell lung cancer (NSCLC). In an open-label phase 3 trial, we compared first-line nivolumab with chemotherapy in patients with programmed death ligand 1 (PD-Ll)-positive NSCLC.

# 研究结果

RESULTS— Among the 423 patients with a PD-L1 expression level of 5% or more, the median progression-free survival was 4.2 months with nivolumab versus 5.9 months with chemo-therapy (hazard ratio for disease progression or death, 1.15; 95% confidence interval [CI], 0.91 to 1.45; P=0.25), and the median overall survival was 14.4 months versus 13.2 months (hazard ratio for death, 1.02; 95% CI, 0.80 to 1.30).

# 研究结论

CONCLUSIONS — Nivolumab was not associated with significantly longer progression-free survival than chemotherapy among patients with previously untreated stage IV or recurrent NSCLC with a PD-L1 expression level of 5% or more.

# 表格相关

Of 1325 patients enrolled in the trial, 541 (41%) underwent randomization, with 271 assigned to receive nivolumab and 270 assigned to receive chemotherapy. A total of 784 patients (59%) did not undergo randomization because their PD-L1 samples could not be evaluated (6% of patients), because the PD-L1 expression level was less than 1% (23%), or because they did not meet other trial criteria (30%). During screening, 746 of 1047 patients (71%) who had PD-L1 results that could be evaluated had a PD-L1 expression of 1% or more. Overall, 530 patients (98% of all the patients who had undergone randomization) received treatment (Fig. S1A and Table S1 in the Supplementary Appendix)

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The baseline characteristics of all the patients who underwent randomization were similar to those of the patients who were included in the primary efficacy analysis (Table 1, and Tables S2 and S3 in the Supplementary Appendix)

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characteristics were generally balanced between the treatment groups. However, in the nivolumab group, the percentage of women was lower than that in the chemo-therapy group (32% vs. 45%), as was the percentage of patients with a PD-L1 expression level of 50% or more (32% vs. 47%); the percentage of patients with liver metastases was slightly higher in the nivolumab group (20% vs. 13%). In addition, patients in the nivolumab group had a greater tumor burden (on the basis of the median sum of target-lesion diameters) than those in the chemotherapy group (Table 1)

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The minimum follow-up for overall survival was 13.7 months, and the median follow-up was 13.5 months (the minimum follow-up was computed as the time from randomization of the last patient to the database lock, and the median follow-up was computed for all the patients from randomization to the last known vital-status date). The median duration of therapy was 3.7 months (range, 0.0 to 26.9+ [the plus sign indicates an ongoing status at the time of the database lock]) in the nivolumab group and 3.4 months (range, 0.0 to 20.9+) in the chemo-therapy group. Details regarding the chemotherapy regimens are provided in Table S4 in the Supplementary Appendix. A total of 38% of treated patients received maintenance pemetrexed. A total of 77 of 267 patients (29%)

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Among the 211 patients with a PD-L1 expression level of 5% or more in the nivolumab group, 92 (44%) received subsequent systemic cancer therapy, and 39 (18%) continued receiving nivolumab at the time of the database lock. Among the corresponding 212 patients in the chemotherapy group, 136 (64%) received subsequent systemic therapy, including 128 (60%) who received nivolumab — 58% as crossover treatment within the trial and 3% in clinical practice after the trial; 1 patient received the drug both within the trial and after the trial (Table S5 in the Supplementary Appendix)

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The response rate among patients with a PD-L1 expression level of 5% or more was 26% in the nivolumab group and 33% in the chemotherapy group (Table 2)

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nivolumab group and the chemotherapy group (2.8 months and 2.6 months, respectively), whereas the median duration of response was more than twice as long with nivolumab as with chemotherapy (12.1 vs. 5.7 months) (Table 2)

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Treatment-related adverse events of any grade occurred in 71% of the patients treated with nivolumab and in 92% of those treated with chemotherapy. The percentage of patients with treatment-related adverse events of grade 3 or 4 was lower with nivolumab than with chemotherapy (18% vs. 51%) (Table 3, and Table S9 in the Supplementary Appendix)

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. The rates of treatment-related serious adverse events were similar in the two groups. Treatment- related adverse events leading to discontinuation of the study drug were 10% with nivolumab and 13% with chemo-therapy (Table 3, and Tables S10, S11, and S12 in the Supplementary Appendix)

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. The most common selected adverse events (those with a potential immunologic cause) that were adjudicated as being related to treatment were skin- related events in the nivolumab group and gastrointestinal events in the chemotherapy group (Table S13 in the Supplementary Appendix)

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