In the global, randomized, open-label, phase 3 KEYNOTE-042 study (NCT02220894), secondary endpoints included progression-free survival (PFS) and ORR per RECIST 9.7 (75.8% vs 19%, p < 0.0001; HR 0.55 (0.37 to 0.80)); 19% (15.2%) vs 1% (4.5%) for ORR; median DOR was 27.6 (range, 6.1–33.2+) months (“+” indicates that response was ongoing at last data assessment). Median time from randomization to database cutoff was 33.0 months (range, 25.6–41.9 months). Overall survival (OS), PFS, and PFS2 were estimated using the Kaplan-Meier method. OS and PFS rates were higher in pembrolizumab than in chemotherapy (Table 2). Efficacy in the ITT Population Effect of pembrolizumab on OS in the ITT population is shown in Figure 2. In the first-line pembrolizumab vs chemotherapy comparison, median OS was superior in the pembrolizumab arm compared with chemotherapy (15.0 vs 11.1 months, HR 0.61 (0.40‒0.91)), across PD-L1 TPS groups (≥50%, ≥20%, ≥1%; Table 2). Consistent with the global KEYNOTE-042 study, these findings support first-line use of pembrolizumab for patients with PD-L1 TPS ≥1% and PD-L1 TPS ≥50% and a manageable safety profile. Immune-mediated AEs and infusion reactions, n (%)

Due to septic shock (n=2), ketoacidosis (n=1), pulmonary embolism (n=1).

PD-L1 TPS ≥50%

Chemotherapy

Pembrolizumab

OS Rate, 12-Month (% (95% CI)

30 36

100

0.55 (0.35‒0.88)

0.61 (0.40‒0.91)

0.56 (0.38‒0.83)

0.55 (0.28‒1.08)

B.

Chemotherapy

Pembrolizumab

No. of Events/

PD-L1 TPS ≥50%

Chemotherapy

Pembrolizumab

Events,

OS

Owing to the software system failure of FastStats, OS was censored for 2 patients (1%)

Table 2. Objective Response, PFS, and PFS2 by PD-L1 TPS in the ITT Population

PD-L1 TPS ≥50%

PD-L1 TPS ≥20%

PD-L1 TPS ≥1%

PD-L1 TPS ≥1%

Table 3. Summary of AE in the As-Treated Population

Sponsorship of Respiratory Medicine, Xiangya Hospital Central South University, Hunan, China; Department of Pulmonary Oncology, Guangdong Lung Cancer Institute, Guangzhou, China; Department of Pulmonary Oncology, Shanghai Pulmonary Hospital, Shanghai, China; Department of Oncology, Zhongshan Hospital, Fudan University, Shanghai, China; Department of Respiratory Medicine, Youan Hospital, Tongji University, Shanghai, China; Guangzhou Medical University Cancer Center, Guangzhou, China; colorectal and pancreatic cancer centers worldwide. This study was supported by Merck & Co., Inc., Kenilworth, NJ, USA.

Note: 642 patients with locally advanced or metastatic NSCLC without prior systemic treatment were randomized to pembrolizumab monotherapy (n = 321) or chemotherapy (n = 321) (1:1); 52 patients were not evaluable due to protocol violations. pembrolizumab monotherapy significantly improved overall survival (OS) over chemotherapy (P = 0.0003; HR 0.61 (0.40–0.91)) and PFS (P = 0.0039; HR 0.60 (0.40–0.91)) in patients with PD-L1 TPS ≥50%. pembrolizumab contributed to meaningful and clinically relevant improvements in OS, ORR, PFS, and PFS2 across all PD-L1 TPS groups evaluated (TPS ≥50%, ≥20%, ≥1%). pembrolizumab also increased the duration of response (DOR) compared with chemotherapy (P = 0.0002).

Conclusions

In this longer-term follow-up (>3 years), first-line pembrolizumab monotherapy continued to improve OS versus platinum-based chemotherapy in Chinese patients with locally advanced or metastatic NSCLC without prior systemic therapy. pembrolizumab was well tolerated and had a manageable safety profile. pembrolizumab improved OS compared with chemotherapy across all PD-L1 TPS subgroups, with an estimated DOR >15 months.

Among patients who completed 35 cycles of pembrolizumab, responses were clinically meaningful and durable.

Pembrolizumab monotherapy was associated with a manageable safety profile.

Consistent with the global KEYNOTE-042 study, these findings support first-line use of pembrolizumab for patients with PD-L1 TPS ≥1% and PD-L1 TPS ≥50% and a manageable safety profile. pembrolizumab contributed to meaningful and clinically relevant improvements in OS, ORR, PFS, and PFS2 across all PD-L1 TPS groups evaluated (TPS ≥50%, ≥20%, ≥1%). pembrolizumab also increased the duration of response (DOR) compared with chemotherapy (P = 0.0002). pembrolizumab was well tolerated and had a manageable safety profile. pembrolizumab improved OS compared with chemotherapy across all PD-L1 TPS subgroups, with an estimated DOR >15 months.

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