Tislelizumab versus docetaxel in patients with previously treated advanced squamous (sq) non-small cell lung cancer (NSCLC): Subanalysis from Phase 3 RATIONALE-303 randomized clinical study

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Background

Tislelizumab is a humanized anti-programmed cell death protein 1 (PD-1) immunoglobulin G4 variant monoclonal antibody with high affinity to PD-1, and was engineered to eliminate the binding function to programmed death-ligand 1 (PD-L1). It is approved for the treatment of advanced squamous (sq) non-small cell lung cancer (NSCLC) with programmed death-ligand 1 (PD-L1) expression ≥ 1%.

Methods

The study design has been described previously4 and is summarized below:

- This RATIONALE-303 trial subanalysis among patients with sq locally advanced or metastatic NSCLC previously treated with platinum-based chemotherapy: Tislelizumab prolonged OS vs docetaxel in patients with sq NSCLC
- Tislelizumab improved PFS and ORR, and prolonged DoR vs docetaxel in patients with sq NSCLC
- Tislelizumab had a generally tolerable and manageable safety profile, in line with the profile of other PD-1/L1 inhibitors, with a very low incidence of 2 Grade 3 TEAEs vs docetaxel.

Results

Conclusions

- In this RATIONALE-303 trial subanalysis among patients with sq locally advanced or metastatic NSCLC previously treated with platinum-based chemotherapy:
  - Tislelizumab prolonged OS vs docetaxel in patients with sq NSCLC
  - Tislelizumab improved PFS and ORR, and prolonged DoR vs docetaxel in patients with sq NSCLC
  - Tislelizumab had a generally tolerable and manageable safety profile, in line with the profile of other PD-1/L1 inhibitors, with a very low incidence of 2 Grade 3 TEAEs vs docetaxel.

- Results were generally consistent with those in the overall ITT population.

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Safety

- 25% of patients experienced Grade ≥ 3 treatment-emergent adverse events (TEAEs) with tislelizumab (36.1%) than docetaxel (29.5%) (Table 2):
  - Treatment-related Grade 3 TEAEs occurred in 38 (14.2%) patients in the tislelizumab treatment arm and 34 (13.5%) patients in the docetaxel treatment arm (Table 2).

Table 2. Summary of TEAE incidence in the sq safety analysis population

- Most common reported adverse events with tislelizumab (9% and 90.3%) and docetaxel (8% and 93.8%) were leukopenia and white blood cell count decrease which was decreased in the tislelizumab group (9.0% vs 93.8%) (Table 2).

Efficacy: Response rates

- ORR was greater with tislelizumab (23.3%) than docetaxel (4.1%) (Figure 3). ORR (explanatory endpoint) was greater with tislelizumab (46.9%) vs docetaxel (37.7%) (Figure 3).

- Median DoR was prolonged with tislelizumab (16.7 months [95% CI: 6.3, not-estimable] vs 6.2 months [95% CI: 2.1, 6.4]) (Figure 4).

References


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