

## Examining the impact of tislelizumab added to chemotherapy on health-related quality of life (HRQoL) outcomes in patients with extensive-stage small cell lung cancer (ES-SCLC)

**Authors:** Ying Cheng<sup>1</sup>, Tai Qin<sup>2</sup>, Yolanda Chen<sup>2</sup>, Bryant Barnes<sup>3</sup>, Gisoo Barnes<sup>3\*</sup>

**Affiliations:** <sup>1</sup>Department of Medical Oncology, Jilin Cancer Hospital, Changchun, China; <sup>2</sup>BeiGene (Beijing) Co., Ltd., Beijing, China; <sup>3</sup>BeiGene (USA) Inc., San Mateo, CA, USA.

### ABSTRACT

**Objectives:** RATIONALE-312 (NCT04005716) demonstrated that tislelizumab plus chemotherapy (n=227) led to a significant improvement in overall survival versus placebo plus chemotherapy (n=230), as first-line treatment for patients with extensive-stage small cell lung cancer (ES-SCLC). Here, we report patient-reported outcomes (PROs) at final analysis.

**Methods:** Eligible adult patients in China with previously untreated ES-SCLC were randomized 1:1 to receive 4 cycles of tislelizumab 200 mg or placebo, with etoposide plus carboplatin or cisplatin intravenously every 3 weeks, followed by tislelizumab 200 mg or placebo as maintenance. PROs assessed health-related quality of life (HRQoL) using the Quality of Life Questionnaire-Core 30 (QLQ-C30) and Quality of Life Questionnaire-Lung Cancer module (QLQ-LC13). A mixed model for repeated measures (MMRM) was performed, using PRO endpoints at baseline, Cycle 4, and Cycle 6. Time to deterioration (TTD) was also examined.

**Results:** Baseline PRO scores were similar in both arms. MMRM analyses demonstrated that patients in each arm improved on the majority of PRO endpoints, in particular global health status/QoL (GHS/QoL), coughing, chest pain, hemoptysis, and dyspnea. Patients in the tislelizumab arm showed a greater improvement in least squares (LS) mean for the QLQ-C30 GHS/QoL domain at Cycle 6 compared with those in the placebo arm (LS mean difference, 4.20, 95% confidence interval [CI]: 0.76-7.64). Only 16-26% of patients in both arms experienced a deterioration event and TTD analysis showed that tislelizumab plus chemotherapy did not increase the risk of clinically meaningful worsening of physical functioning, coughing, or chest pain.

**Conclusions:** PRO outcomes between the treatment arms were comparable in this population of patients with previously untreated ES-SCLC, with improvements observed in the tislelizumab arm on the key GHS/QoL domain. These results, along with previous efficacy and safety data, support tislelizumab plus chemotherapy as first-line treatment for ES-SCLC.