The study met its primary objective of prolonging IRC duration of response (DoR), and safety.

**Background**

- Tislelizumab, a monoclonal antibody with high affinity and binding specificity for programmed cell death protein 1, was specifically engineered to minimize Fcy receptor binding on macrophages.2

- In patients with advanced nonsquamous (ns) small-cell lung cancer (NSCLC), interim results from the open-label, multicenter, randomized phase 3 RATIONALE-304 trial (NCT03663205) demonstrated significantly prolonged progression-free survival (PFS) and an improved tumor response rate with first-line tislelizumab plus platinum-based chemotherapy compared with platinum-based chemotherapy alone. Here, we report updated results from the final analysis (FA) of RATIONALE-304.

**Methods**

- **Patients** aged 18-75 years with treatment-naive, stage IIIB (not amenable to curative surgery/radiotherapy) or stage IV nsNSCLC were enrolled.

- **Patients** were randomized (2:1) to open-label
  - **Arm A:** Tislelizumab 200 mg intravenously every 3 weeks plus platinum-based chemotherapy for 4 cycles, followed by maintenance tislelizumab plus pemetrexed; or
  - **Arm B:** Platinum-based chemotherapy alone for 4-6 cycles, followed by maintenance pemetrexed.

- **Primary endpoint:** PFS, assessed by independent review committee (IRC) in the intention-to-treat (ITT) analysis set.

- **Secondary endpoints** included: overall survival (OS), IRC-assessed objective response rate (ORR) by Response Evaluation Criteria in Solid Tumors version 1.1, and duration of response (DoR), and safety.

**Scan the QR code for full methodology from the previously published interim analysis.**

**Results**

**Patient Disposition and Baseline Characteristics**

- Between July 23, 2018, and July 31, 2019, 334 patients were randomized to Arm A (n=223) or Arm B (n=111).

- Demographics and baseline characteristics were well balanced between arms:
  - Overall, median age was 61 years, most patients were male (74.0%), and most had stage IIIB at baseline (81.2%).

- Tumor programmed death-ligand 1 (PD-L1) membrane expression was <1% or unevaluable in 43.1% of patients, 1-49.0% in 24.0%, and ≥50% in 24.0%, and ≥50% in 24.0%.

- More patients remained on assigned treatment in Arm A (24.2%) than Arm B (5.4%).

**Efficacy**

**PFS**

The study met its primary objective of prolonging IRC assessed PFS in the tislelizumab plus chemotherapy arm (Arm A) versus chemotherapy alone (Arm B) at the interim analysis.

- The PFS improvement in Arm A versus Arm B remained consistent at the FA cutoff date (October 26, 2020); PFS hazard ratio (HR) (0.63) (95% confidence interval [CI]: 0.47, 0.86) (Figure 1).

- PFS benefit was observed in all PD-L1 expression subgroups (Table 1).