

## **RATIONALE 307: Tislelizumab (TIS) plus chemotherapy (chemo) vs chemo alone as first-line (1L) treatment for advanced squamous non-small cell lung cancer (sq NSCLC) in patients (pts) who were smokers vs non-smokers**

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### **Background**

Primary results from the Phase 3 RATIONALE-307 study (NCT03594747) showed efficacy and a manageable safety/tolerability profile for TIS, an anti-programmed cell death protein 1 monoclonal antibody, plus chemo, as 1L treatment for sq NSCLC. We report results based on smoking status.

### **Methods**

Eligible pts (18–75 years) who were treatment-naïve for locally advanced or metastatic sq NSCLC were stratified by disease stage and programmed death-ligand 1 expression, and randomized 1:1:1 to Arm A: TIS 200 mg + paclitaxel (P) 175 mg/m<sup>2</sup> and carboplatin (C) AUC 5 (every 3 weeks [Q3W], day [D] 1); Arm B: TIS + nab-paclitaxel 100 mg/m<sup>2</sup> (Q3W, D 1, 8 and 15) + C (Q3W, D 1); or Arm C: P + C (Q3W, D 1). Chemo was administered for 4–6 cycles. Progression-free survival (PFS) by independent review committee (IRC), objective response rate (ORR) by IRC, and safety were assessed in pts who were smokers (former/current) and non-smokers.

### **Results**

301 pts who were smokers with a median age of 62 years and 59 pts who were non-smokers with a median age of 58 years were randomized. Longer PFS and higher ORR were reported with TIS plus chemo vs chemo alone regardless of smoking status (**Table**). Treatment emergent adverse events (TEAEs) are summarized in the **Table**.

### **Conclusions**

Clinically meaningful improvements in PFS and ORR were observed with TIS plus chemo in pts with advanced sq NSCLC, irrespective of smoking status. The safety and efficacy profile of TIS plus chemo was consistent with the overall population of this Phase 3 study.

**Table**

	Smokers			Non-smokers		
	A (n=96)	B (n=107)	C (n=98)	A (n=24)	B (n=12)	C (n=23)
<b>n, (95% CI)</b>						
Median PFS, months	7.6 (5.59, 10.41)	7.6 (5.62, 9.86)	5.5 (4.17, 5.78)	7.5 (5.45, 7.82)	NE (4.17, NE)	5.4 (2.79, 5.59)
Hazard ratio*	0.534 (0.363, 0.786)	0.556 (0.384, 0.803)	-	0.475 (0.226, 1.000)	0.119 (0.027, 0.533)	-
ORR, %	75.0 (65.1, 83.3)	73.8 (64.4, 81.9)	50.0 (39.7, 60.3)	62.5 (40.6, 81.2)	83.3 (51.6, 97.9)	47.8 (26.8, 69.4)
	<b>n=96</b>	<b>n=106</b>	<b>n=94</b>	<b>n=24</b>	<b>n=12</b>	<b>n=23</b>
<b>n (%)</b>						
Pts with ≥ 1 TEAE	96 (100.0)	105 (99.1)	94 (100.0)	24 (100.0)	12 (100.0)	23 (100.0)
Grade ≥ 3	87 (90.6)	91 (85.8)	82 (87.2)	19 (79.2)	11 (91.7)	16 (69.6)
Serious	36 (37.5)	42 (39.6)	23 (24.5)	8 (33.3)	3 (25.0)	6 (26.1)

\*Unstratified