Transportability of RATIONALE-315 trial outcomes to the European patient population in resectable non-small cell lung cancer

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ABSTRACT

Background: In the RATIONALE-315 (NCT04379635) trial, neoadjuvant tislelizumab plus chemotherapy followed by adjuvant tislelizumab (TIS) resulted in a statistically significant improvement in efficacy versus neoadjuvant chemotherapy + placebo followed by adjuvant placebo (nCT + PBO), in patients with resectable stage II-IIIA non-small cell lung cancer (NSCLC). RATIONALE-315 was conducted in China; this analysis evaluated the transportability of efficacy outcomes to the European population.

Methods: A protocol-driven targeted literature review (TLR) was conducted to identify literature reporting baseline characteristics of stage II-IIIA NSCLC patients in European real-world populations. All retrieved abstracts and full texts were screened according to predetermined criteria. The final studies selected were considered the most suitable to define the target European populations. Outcome regression analyses were conducted to estimate the transportability of treatment effects observed in RATIONALE-315 for event-free survival (EFS), major pathological response (MPR) and pathological complete response (pCR) to the European population.

Results: After screening 178 articles and 8 gray literature sources, 10 studies were included in the TLR. Two studies, which enrolled patients in the defined target populations, were deemed relevant for the statistical analyses. EFS for RATIONALE-315 (HR: 0.56 [0.40-0.79]) was comparable to the predicted results for the target European population 1 (HR: 0.57 [95% CI: 0.25-1.34]) and target population 2 (HR: 0.63 [0.35-1.13]). Similarly, MPR for RATIONALE-315 indicated a substantial benefit of TIS versus nCT + PBO (OR: 7.49 [4.75-11.82]), and this was aligned with the predicted MPR results (population 1 OR: 3.39 [1.07-11.52]; population 2 OR: 10 [4.19-25.71]). Similar results were observed for pCR (RATIONALE-315 OR: 11.54 [6.18-21.54], versus predicted ORs for European target population 1: 8.95 [1.92-58.88] and population 2: 12.41 [4.18-46.85]).

Conclusions: These analyses demonstrated that the treatment effects of TIS versus nCT + PBO observed in the RATIONALE-315 trial are applicable to European patients with resectable NSCLC.