

## Anchor-Based Thresholds for Meaningful within-Patient Change in the Phase 3 Trial to Evaluate Tislelizumab for the Treatment of 2/3L NSCLC

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**OBJECTIVES:** Although recent FDA oncology guidance has emphasized the importance of an anchor-based approach for estimating thresholds of meaningful within-patient change (MWPC), there is little published work reporting results based on the implementation of this approach for legacy instruments. This research applies the anchor-based approach for estimating the MWPC thresholds for EORTC QLQ-C30 and EORTC QLQ-LC13.

**METHODS:** Data (N=805) from the BGB-A317-303 Phase 3 clinical trial (NCT03358875) evaluating tislelizumab for the treatment of 2/3L non-small cell lung cancer (NSCLC) was analysed. The EORTC QLQ-C30 global health/QoL status scale treatment yielding 5 anchor groups: "Deteriorated, 2 or more categories," "Deteriorated, 1 category," "Maintained," "Improved, 1 category," and "Improved, 2 or more categories." Change from baseline at Cycle 5 Day 1 (CFBLC5D1) scores were computed for each domain. MWPC thresholds were estimated as mean and median CFBLC5D1 for each domain stratified by anchor level.

**RESULTS:** Due to space constraints, only the results of the QLQ-LC13 score of "Pain in Arm or Shoulder" are presented here. Fourteen (3.2%) patients were in the anchor group "Deteriorated, 2 or more categories," and the mean and median change scores were 14.29 and 16.67, respectively. These thresholds corresponded to approximately 1/2 category change on the raw scale. Additionally, 30 (6.8%) patients were in the anchor group "Improved, 2 or more categories" and the mean and median change scores were -15.56 and 0.00, respectively. Thresholds for all domains will be presented.

**CONCLUSIONS:** To satisfy the FDA requirement that MWPC thresholds have a minimum value of a 1-point change on a domain score, any EORTC transformed score threshold must be 33.33 points of change or greater. Thresholds acceptable under current regulatory framework must, therefore, routinely exceed the historic EORTC thresholds of 5- to 10-point change.

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