**Methods**

**Overall Design and Study Objectives**
- The multi-center, double-blind, placebo-controlled, randomized, phase 3 study (NCT04397543; BGB-A317-307) is being conducted in about 30 sites with approximately 380 patients and is designed to compare the efficacy of neoadjuvant tislelizumab or placebo plus platinum-containing chemotherapy followed by surgery and adjuvant tislelizumab or placebo for patients with resectable stage II or IIIA NSCLC (Figure 3).

**Figure 3: Study Design**

- The dual primary endpoints are major pathological response rate as assessed by blinded independent pathology review (MRP3) and event-free survival as assessed by blinded independent central review (EFS).
- Secondary endpoints will include overall survival (OS), OS-directed response rate (complete or partial response), pathological complete response rate by blinded independent pathology review, disease-free survival by blinded independent central review, investigator-assessed EFS, safety/tolerability profile, as well as health-related quality-of-life measures.

**Study Population**
- Key inclusion/exclusion criteria are outlined in Table 1.

**Table 1: Patient Eligibility**

**Inclusion Criteria**

- Adults (aged ≥18 years)
- Histologically confirmed stage II/IIIA NSCLC
- Eligible for a R0 resection with curative intent
- ≤1 measurable/evaluable lesion per RECIST v1.1
- ECOG performance status score ≤1
- No prior systemic therapy
- No active malignancy ≤2 years before study entry except for NSCLC or any local recurrence that has been treated curatively
- Adequate bone marrow, organ, and organ function

**Exclusion Criteria**

- Known EFRG mutation or ALK gene translocations
- Prior treatment with - Chemo- or radiotherapy for stage II or III NSCLC
- An antibody toward an immune checkpoint pathway inhibitor or any other checkpoint blockers or other immunomodulatory drug ≤14 days before randomization
- History of intestinal lung disease, nonmucinous pneumonia, or ulcerated lung disease
- Any active malignancy ≤2 years before randomization except for NSCLC, or any locally recurring cancer that has been treated curatively

**Study Assessments, Populations, and Statistical Analysis**

- Tumor assessments will occur at baseline, before Cycle 3 of neoadjuvant treatment and surgery, and then every 3 months after surgery for the first 2 years; assessments will occur every 6 months from Years 3.5 and annually thereafter.
- The dual primary endpoints of MRP3 and EFS will be assessed using the Cochran-Mantel-Haenszel chi-square test methodology and the stratified log-rank test methodology, respectively.
- All efficacy analyses will be performed in the intent-to-treat analysis set, defined as all patients who have been randomized to treatment.
- Safety/tolerability will be assessed by evaluating the incidence and severity of adverse events (AEs), physical examinations, vital signs, electrocardiograms, and laboratory test results.

- Adverse events are defined as those reported ≤30 days after the last dose of study drug or until initiation of new systemic anticancer treatment, whichever occurs first.

**CONFLICT OF INTEREST**

No conflicts of interest.

**ACKNOWLEDGMENTS**

The investigators listed are the independent scientific review staff and do not receive compensation from Biogen, Inc. who have substantially contributed to the development of this presentation. For a complete listing of investigators, please refer to the abstract.

The following individuals provided medical writing assistance by Agnieszka Laskowski, PhD, and Elizabeth Hermans, PhD, from Peloton Advantage, LLC, an OPEN Health company (Parsippany, NJ).

**REFERENCES**


