**INTRODUCTION**

- Many patients with advanced non-small cell lung cancer (NSCLC) initially benefit from multi-antitumor growth factor receptor (HER) inhibitors (TAs) in the second- or third-line setting, but subsequently develop resistance to this treatment.
- Human epidermal growth factor receptor 3 (HER3) is a key dimerization partner of HER2 and HER4 and plays a role in survival and chemoresistance.
- HER3-mediated signaling is associated with poor prognosis and chemo-resistance, and HER3-targeted agents have been developed to treat HER2-positive and -negative tumors.
- Patritumab is a fully human anti-HER3 monoclonal antibody that binds to the HER3 receptor.

**STUDY DESIGN**

- **Study Design:**
  - A 4-arm, open-label, phase 2 study with a randomized phase A/B design that will enroll 120 patients (NCT01211483).
  - **Part A:** Aimed at identifying the optimal dose of patritumab in combination with erlotinib in patients with NSCLC.
  - **Part B:** Follows Part A and evaluates the combination of patritumab and erlotinib in patients with HRG-high status.

**KEY INCLUSION CRITERIA**

- **Part A:**
  - Histologically confirmed NSCLC with either metastatic (stage IV) disease or non-metastatic disease that is locally advanced or unresectable.
  - ≥18 years of age.
  - Eastern Cooperative Oncology Group (ECOG) performance status 0–1.
  - At least 1 prior line of chemotherapy (completed ≥14 days before study drug treatment), or palliative radiation therapy.
  - Adequate organ function.

- **Part B:**
  - History of NSCLC with either metastatic (stage IV) disease or non-metastatic disease that is locally advanced or unresectable.
  - ≥18 years of age.
  - Eastern Cooperative Oncology Group (ECOG) performance status 0–1.
  - At least 2 prior lines of chemotherapy (completed ≥14 days before study drug treatment), or palliative radiation therapy.
  - Adequate organ function.

**SUMMARY**

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