A Study to Learn More About How Well Sevabertinib (BAY 2927088) Works and How Safe it is Compared With Standard Treatment, in Participants Who Have Advanced Non-small Cell Lung Cancer (NSCLC) With Mutations of the Human Epidermal Growth Factor Receptor 2 (HER2)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Participant must be ≥18 years of age or over the legal age of consent in countries where that is greater than 18 years at the time of signing the informed consent. * Documented histologically or cytologically confirmed locally advanced non-squamous NSCLC, not suitable for definitive therapy or metastatic non-squamous NSCLC at screening (small cell or mixed histologies are excluded) (Stage III-IV NSCLC). * Documented activating HER2 mutation in the tyrosine kinase domain (TKD) assessed by tissue molecular test in a CLIA-certified (US sites) or an equally accredited (outside of the US) local laboratory. However, participants may be included at the discretion of the investigator if the laboratory performing the assay is not CLIA or similar certified but the laboratory is locally accredited. * No prior systemic therapy for locally advanced or metastatic disease. No prior treatment with a HER2 ex20ins-targeted therapy (e.g. poziotinib, trastuzumab deruxtecan). Participants who received adjuvant or neoadjuvant therapy are eligible if the adjuvant/neoadjuvant therapy was completed at least 12 months prior to the start of screening. * Eligible to receive treatment with the selected platinum-based doublet-chemotherapy (i.e. cisplatin/pemetrexed or carboplatin/pemetrexed) and pembrolizumab in accordance with the SmPC/Product Information.

Exclusion Criteria:

* Known history of prior malignancy except if the participant has undergone potentially curative therapy with no evidence of that disease recurrence for five years since initiation of that therapy. Exception: the following cancer types are acceptable within five years if curatively treated or under surveillance: * a. in situ cancers of cervix, breast, or skin, * b. superficial bladder cancer (Ta, Tis and T1), * c. limited-stage prostate cancer, * d. basal or squamous cancers of the skin. * Tumors with targetable alterations with approved available therapy, with the exception of HER2 mutation in the TKD. * Inability to discontinue treatment with chronic systemic corticosteroids. Participants who require intermittent use of bronchodilators, inhaled steroids, or local steroid injections would not be excluded from the study. Replacement therapy (e.g., physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is acceptable, provided that the dose is stable for \>4 weeks prior to planned start of study intervention. * Pre-existing peripheral neuropathy that is Grade ≥2 by CTCAE (v5.0). * History of severe hypersensitivity reaction to treatment with a monoclonal antibody. * Prior radiotherapy outside of the brain within 21 days before of planned start of study intervention. Participants must have recovered from all radiation-related toxicities and not require corticosteroids.

Conditions & Interventions

Interventions:
DRUG: BAY2927088, DRUG: Pembrolizumab, DRUG: Cisplatin, DRUG: Carboplatin, DRUG: Pemetrexed
Conditions:
Advanced Non-small Cell Lung Cancer, HER2 Mutation
Keywords:
NSCLC, ERBB2 mutation

More Information

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