Papillon (Janssen)

A Study of Combination Amivantamab and Carboplatin-Pemetrexed Therapy, Compared With Carboplatin-Pemetrexed, in Participants With Advanced or Metastatic Non-Small Cell Lung Cancer Characterized by Epidermal Growth Factor Receptor (EGFR) Exon 20 Insertions.

This is the trial summary as assessed on clinicaltrials.gov on 10/03/2021.

Minor changes in the protocol may occur. You can check this on this direct link: https://www.clinicaltrials.gov/ct2/show/NCT04538664

Trial Design:

Arm	Intervention
Experimental: Arm A	Amivantamab – IV C1-C2 1400 mg (1750 mg when >80 kg) C3-… 1750 mg (2100 mg when >80 kg) Carboplatin – IV (4 cycles) AUC 5 Pemetrexed – IV 500 mg/m^2
Experimental: Arm B	Carboplatin – IV (4 cycles) AUC 5 Pemetrexed – IV 500 mg/m^2

Inclusion criteria:

- Participant must have histologically or cytologically confirmed, locally advanced or metastatic, nonsquamous non-small cell lung cancer (NSCLC) with documented primary epidermal growth factor receptor (EGFR) Exon 20ins activating mutation
- Participant must have measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
- Participant must have Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1

- Participant must agree to genetic characterization of tumor status through the required pretreatment tumor biopsy (or submission of equivalent archival material), as well as baseline and periodic blood samples for analysis of tumor mutations in the bloodstream
- A female participant of childbearing potential must have a negative serum or urine test at screening and within 72 hours of the first dose of study treatment and must agree to further serum or urine pregnancy tests during the study

Exclusion criteria:

- Participant has evidence of synchronous NSCLC with an EGFR mutation other than EGFR Exon 20ins
- Participant has untreated brain metastases (a participant with definitively, locally treated metastases who is clinically stable, asymptomatic, and off corticosteroid treatment for at least 2 weeks prior to randomization is eligible)
- Participant has history of spinal cord compression that has not been treated definitively with surgery or radiation
- Participant has a medical history of interstitial lung disease (ILD), including drug-induced ILD, or radiation pneumonitis
- Participant has a contraindication to the use of carboplatin or pemetrexed (refer to local prescribing information for each agent). Participant has a history of hypersensitivity to, or cannot take, vitamin B12 or folic acid