PAPILLON

# The PAPILLON Research Study

## An Overview for Healthcare Professionals

*The information contained in this download is intended for healthcare providers only.*
*This is not to be used with potential participants.*

## About the PAPILLON Study

The purpose of the PAPILLON research study is to determine whether the investigational medication, amivantamab, in combination with carboplatin-pemetrexed chemotherapy compared to chemotherapy alone is safe and effective in adults with locally advanced or metastatic non-small-cell lung cancer (NSCLC) that have epidermal growth factor receptor (EGFR) Exon 20 insertion mutations. Amivantamab is a fully human IgG1-based investigational bispecific antibody directed against EGFR and MET tyrosine kinase receptors.

This mutation creates a unique protein structure that prevents effective binding of targeted therapies. Therefore, there are no currently approved targeted therapies for this group of patients.

## Your patients may be eligible if they meet the following inclusion criteria:

- ≥ 18 years of age
- Histologically or cytologically confirmed, locally advanced or metastatic, non-squamous NSCLC with documented primary EGFR Exon 20 insertion mutation
- Have not received any prior systemic treatment for locally advanced or metastatic disease*
- Measurable disease according to RECIST v1.1
- ECOG performance status of 0 or 1
- Must agree to tumor biopsy or submit archival tissue for genetic testing
- Must demonstrate adequate organ and bone marrow function as follows:
  - Hemoglobin ≥10 g/dL
  - Absolute neutrophil count ≥1.5x109/L
  - Platelets ≥100x109/L
  - Liver function tests (ALT and AST) ≤3×upper limit of normal (ULN)
  - Total bilirubin ≤1.5xUL
  - Creatinine clearance >50 mL/min

**Prior TKI therapy for a maximum of 8 weeks, with documented lack of response is allowed*

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## What will happen during the PAPILLON Study?

- Eligible patients will be randomized 1:1 to Arms A and B
  - Patients in Arm A will receive the investigational medication (intravenous infusion) and combination of chemotherapy (intravenous infusion)
  - Patients in Arm B will receive chemotherapy (intravenous infusion) alone and can crossover to monotherapy amivantamab upon disease progression
- All patients will receive study medication in 21-day cycles
- Participation will include regularly scheduled study visits for tests and procedures

*Each study participant will continue on 21-day treatment cycles until their NSCLC begins to progress, unacceptable toxicity, the study ends, or they discontinue for other reasons.*

**There are study clinics located throughout the United States. Find a location near you by visiting https://janssenoncologyclinicaltrials.com/lc/locations**

**To see a list of participating study clinics in over 20 countries globally, visit https://janssenoncologyclinicaltrials.com/lc/countries**

**If you have a patient with NSCLC with EGFR Exon 20 insertion mutations who may be a candidate, please speak to them about the possibility of participating in this research study.**

**Have your patients call 1-800-811-1923 or visit JanssenOncologyClinicalTrials.com/lungcancer to see if they are eligible and to learn more about the PAPILLON Study.**

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