CHRYSALIS

The CHRYSALIS Clinical 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.

In non-small-cell lung cancer (NSCLC), growth factor pathway deregulation plays a key role in oncogenesis. However, over time, acquired resistance to TKI therapy is consistently observed.[1,2]

About the CHRYSALIS Study

The CHRYSALIS Study is evaluating the safety and effectiveness of an investigational medication or a combination of two investigational medications for different groups of people with NSCLC. The study is currently enrolling adults with advanced or metastatic NSCLC with a primary MET Exon 14 skipping mutation (MET Exon 14).

In addition, it is enrolling adults with adenocarcinoma (WT-adeno) or squamous cell carcinoma (WT-squam) histology who have wild-type EGFR/wild-type ALK with demonstrated expression of EGFR protein, MET protein, or both proteins (via centralized immunohistochemistry).

Your patients may be eligible for the CHRYSALIS Study if they meet the following criteria:

- ≥18 years of age
- Histologically or cytologically confirmed NSCLC that is metastatic or unresectable
- Documented primary MET Exon 14 skipping mutation
- Wild-type EGFR and ALK, who have adenocarcinoma or squamous cell histologies with positive EGFR and/or MET expression
- Have progressed on standard of care therapy, or will be ineligible for or have refused all other currently available approved therapeutic options
- Organ and bone marrow function as follows:
  - Hemoglobin ≥10 g/dL
  - Absolute neutrophil count: ≥1.5 x 10^9/L
  - Platelets: ≥75 x 10^9/L
  - Liver function tests (ALT and AST): ≤3 × upper limit of normal (ULN)
  - Total bilirubin: ≤1.5 x ULN
  - Serum creatinine <1.5 x ULN or if available, calculated or measured creatinine clearance >50 mL/min/1.73 m^2
- Tumor tissue required for study enrollment
- ECOG performance status of 0 or 1

EGFR, epidermal growth factor receptor; MET, hepatocyte growth factor receptor; ALK, anaplastic lymphoma kinase

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What will happen during the CHRYSALIS Study?

- Participants will receive the investigational medications while completing various study tests and procedures.
  - All participants will receive amivantamab by intravenous infusion (participants in the MET Exon 14 and wild-type cohorts will receive amivantamab as an investigational monotherapy).
- Dosing will take place once a week for the first four weeks of investigational medication cycle 1, then every two weeks during each subsequent cycle, with each cycle lasting 28 days.
- The study duration will vary from person to person depending on the response to amivantamab.
- Each study participant will continue on 28-day investigational medication cycles until their NSCLC begins to progress, unacceptable toxicity occurs, 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/c/hcp-locations. To see a list of participating study clinics in over 11 countries globally,visit https://janssenoncologyclinicaltrials.com/lc/c/hcp-countries.

If you have a patient with NSCLC who may be a candidate for MET Exon 14, WT-Adeno, or WT-Squam based on the criteria above, please discuss the possibility of participating in this clinical research study.

Have your patients call **1-844-455-1045** or visit
JanssenOncologyClinicalTrials.com/lungcancer
to see if they are eligible and to learn more
about the **CHRYSALIS** Study.

SOURCE:
[1]*https://pubmed.ncbi.nlm.nih.gov/32014348/*
[2]*https://www.sciencedirect.com/science/article/pii/S1556086416311790*

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