CHRYSALIS-2

The CHRYSALIS 2 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. Small molecule tyrosine kinase inhibitors (TKI) have demonstrated significant clinical benefit in the presence of certain activating mutations. However, acquired resistance to TKI therapy has been inevitable due primarily to second site mutations. However, over time, acquired resistance to TKI therapy is consistently observed.[1,2]

About the CHRYSALIS 2 Study (global expansion only)

The purpose of the CHRYSALIS 2 Study is to evaluate the safety profile, efficacy, and pharmacokinetics of lazertinib, an investigational medication, in an investigational combination with amivantamab, or in an investigational combination with carboplatin and pemetrexed in participants with advanced NSCLC.

The CHRYSALIS 2 Study has multiple cohorts to characterize the safety, tolerability, and antitumor activity of these investigational medications in those with a variety of mutations.

Your patients may be eligible for the CHRYSALIS 2 Study if they meet the following criteria:

18+ ≥18 years of age

Histologically or cytologically confirmed NSCLC with a previously identified mutation:

- Uncommon non-Exon 20 insertion activating mutations including S768I, L861Q, and G719X (other mutations may be considered)

Organ and bone marrow function as follows:

- Hemoglobin: ≥9 g/dL (≥10 g/dL for certain cohorts)
- Absolute neutrophil count: $\geq 1.5\times10^9$/L
- Platelets: $\geq 75\times10^9$/L ($\geq 100\times10^9$/L for certain cohorts)
- Liver function tests (AST and ALT): ≤3× upper limit of normal (ULN)
- Total bilirubin: ≤1.5×ULN
  - Those with Gilbert's syndrome can enroll if conjugated bilirubin is within normal limits

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What will happen during the CHRYSALIS 2 Study?

- Participants will receive the investigational medication(s) while completing various study tests and procedures.
  - All participants will receive lazertinib, in investigational combination with amivantamab or in an investigational combination with other medications.
- Investigational medications will be administered in 28-day cycles.
- The study duration will vary from person to person depending on the response to investigational medication(s).
- Each study participant will continue on their assigned 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/locations. To see a list of participating study clinics globally, visit https://janssenoncologyclinicaltrials.com/lc/countries.

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

Have your patients call **844-455-1045**
or visit **JanssenOncologyClinicalTrials.com/lungcancer**
to see if they are eligible and to learn more
about the **CHRYSALIS 2** Study.

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

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Expansion Cohort Designation

Advanced or metastatic NSCLC characterized by an **uncommon non-Exon 20ins activating mutation (including but not limited to S768I, L861Q, and G719X)**. Additional uncommon EGFR mutations/alterations, beyond those listed above, may be considered for enrollment after agreement with the medical monitor.

May be treatment naïve or have been treated with one prior line of therapy which must be a first- or second-generation TKI (ie, gefitinib, erlotinib, afatinib) in the most recent line of therapy. Prior chemotherapy is allowed if administered prior to EGFR-TKI therapy, or as the only systemic anti-cancer therapy prior to study enrollment. **Up to 2 lines of prior systemic anti-cancer treatment are allowed.**

Allows:

- Treatment naïve → NSC1001
- First- or second-generation TKI → NSC1001
- Chemotherapy → First- or second-generation TKI → NSC1001
- Chemotherapy → NSC1001