

Protocol LXH254, LTT462

A Phase Ib, open-label, multicenter study of oral LXH254 in combination with oral LTT462 in adult patients with advanced or metastatic KRAS or BRAF mutant Non-Small Cell Lung Cancer.

This is the trial summary as assessed on clinicaltrials.gov on 12/04/2017.

Minor changes in the protocol may occur. You can check this on this direct link:

<https://clinicaltrials.gov/ct2/show/NCT02974725?term=CLXH254X2102&rank=1>

Trial Design :

A Phase Ib, Open-label, Multicenter Study of Oral LXH254 in Combination With Oral LTT462 in Adult Patients With Advanced or Metastatic KRAS or BRAF Mutant Non-Small Cell Lung Cancer.

To characterize safety and tolerability of LXH254 and LTT462 combination and identify a recommended dose and regimen.

Inclusion Criteria:

Patients must have advanced or metastatic NSCLC

Presence of KRAS or BRAF mutation in tumor tissue

All patients participating in this clinical trial must have progressed following standard therapy or, in the opinion of the Investigator, no effective standard therapy exists, is tolerated, appropriate or is considered equivalent to study treatment.

ECOG (Eastern Cooperative Oncology Group) performance status ≤ 2

Exclusion Criteria:

Dose expansion -

Group 1: Prior treatment with a RAFi (including any BRAFi and pan-RAFi), MEKi and/or ERKi.

Group 2: Prior treatment with an ERKi and/or a pan-RAFi.

History or current evidence of retinal vein occlusion (RVO) or current risk factors for RVO.

Any medical condition that would, in the investigator's judgment, prevent the patient's participation in the clinical study due to safety concerns or compliance with clinical study procedures.

Patients receiving proton pump inhibitors (PPI) which cannot be discontinued 3 days prior to the start study treatment and for the duration of the study.

Patients with Gilbert's syndrome or other heritable diseases of bile processing.

Other protocol-defined inclusion/exclusion criteria may apply.