Protocol LDK378-NIVOLUMAB CLDK378A2120C

A multi-center, open-label study to assess the safety and efficacy of combination ceritinib (LDK378) and nivolumab in adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer.

This is the trial summary as assessed on clinicaltrials.gov on 13/05/2015.

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

https://clinicaltrials.gov/ct2/results?term=CLDK378A2120C&Search=Search

Trial Design :

This is an open label multi-center trial to determine the safety and efficacy of ceritinib in combination with nivolumab in ALK-positive NSCLC patients.

Inclusion Criteria:

Histologically or cytologically confirmed diagnosis of NSCLC that carries an ALK rearrangement

Stage IIIB or IV NSCLC or relapsed locally advanced or metastatic NSCLC

Presence of at least one measurable lesion as defined by RECIST 1.1

Patients who have received prior chemotherapy, other ALK inhibitors, biologic therapy, or other investigational agents, must have recovered from all toxicities related to prior anticancer therapies to grade ≤1 (CTCAE v 4.03). Patients with grade ≤ 2 peripheral neuropathy or any grade of alopecia, fatigue, nail changes or skin changes are allowed to enter the study

Patient has a WHO performance status 0-1

Exclusion Criteria:

Presence or history of a malignant disease other than NSCLC that has been diagnosed and/or required therapy within the past 3 years

Patients with an active, known or suspected autoimmune disease

Unable or unwilling to swallow tablets or capsules

Patient has other severe, acute, or chronic medical conditions including uncontrolled diabetes mellitus or psychiatric conditions or laboratory abnormalities that in the opinion of the Investigator may increase the risk associated with study participation, or that may interfere with the interpretation of study results