Protocol BFAST

A phase II/III multicentre study evaluating the efficacy and safety of multiple targeted therapies as treatments for patients with advanced or metastatic non-small cell lung cance (NSCLC) harbouring actionable somatic mutations detected in blood (B-Fast: blood-first assay screening trial).

This is the trial summary as assessed on clinicaltrials.gov on 18/12/2017

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

https://clinicaltrials.gov/ct2/show/NCT03178552?term=BO29554&recrs=ab&rank=1

Trial Design :

This is a phase 2/3, global, multicenter, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in combination in participants with unresectable, advanced or metastatic NSCLC determined to harbor oncogenic somatic mutations or positive by tumor mutational burden (TMB) assay as identified by two blood-based next-generation sequencing (NGS) circulating tumor DNA (ctDNA) assays.

Inclusion Criteria:

Histologically or cytologically confirmed diagnosis of unresectable Stage IIIb not amenable to treatment with combined modality chemoradiation (advanced) or Stage IV (metastatic) NSCLC

Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2

Measurable disease

Adequate recovery from most recent systemic or local treatment for cancer

Adequate organ function

Life expectancy greater than or equal to (>/=) 12 weeks

For female participants of childbearing potential and male participants, willingness to use acceptable methods of contraception

Exclusion Criteria:

Inability to swallow oral medication

Women who are pregnant or lactating

Active or untreated CNS metastases as determined by computed tomography (CT) or magnetic resonance imaging (MRI) evaluation during screening and prior radiographic assessments

History of other malignancy within 5 years prior to screening, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, in situ ductal adenocarcinoma of the breast, in situ prostate cancer, limited stage bladder cancer, Stage I uterine cancer, or other cancers from which the patient has been disease-free for at least 2 years

Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or greater), myocardial infarction, or cerebrovascular accident within 3 months prior to randomization, unstable arrhythmias, or unstable angina

Known human immunodeficiency virus (HIV) positivity or autoimmune deficiency syndrome (AIDS)-related illness

Either a concurrent condition or history of a prior condition that places the patient at unacceptable risk if he/she were treated with the study drug or confounds the ability to interpret data from the study

Inability to comply with other requirements of the protocol