

A Phase 3 open-label, randomized, active-controlled, multicenter trial to evaluate the efficacy and safety of orally administered BAY 2927088 compared with standard of care as a first-line therapy in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with HER2-activating mutations.

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- locally advanced non small cell lung cancer (NSCLC) not suitable for definitive therapy or recurrent or metastatic NSCLC at screening - treatment with at least one prior systemic therapy for advanced disease - people who do not have standard of care access due to any reason, are intolerant to, or are not eligible for - documented activating EGFR and/or HER2 mutation - may be unable to do physically strenuous activity but walking and able to carry out work of a light or sedentary nature, e.g., light house work, office work - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- history of primary brain or leptomeningeal disease (symptomatic or asymptomatic), presence of symptomatic central nervous system (CNS) metastases, or CNS metastases that require local treatment (such as radiotherapy or surgery) - history of congestive heart failure (CHF) Class >II according to the New York Heart Association (NYHA) Functional Classification or serious cardiac arrhythmias requiring treatment (e.g. ventricular arrhythmias, atrial fibrillation) - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:

Drug: BAY2927088_formulation A, Drug: BAY2927088_formulation B_1, Drug: BAY2927088_formulation B_2

Conditions:

Cancer

Keywords:

lung cancer, non small cell lung cancer, NSCLC, Clinics and Surgery Center (CSC)

More Information

Description: This clinical research study is being conducted to gain knowledge about a new drug called BAY 2927088 for a type of cancer called advanced non-small cell lung cancer, which cannot be removed with surgery or has spread to other parts of the body, and has a mutation in the HER2 gene.

Study Contact: Robert Kratzke - kratz003@umn.edu

Principal Investigator: Robert Kratzke

Phase: PHASE1

IRB Number: STUDY00023722

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