DAREON™-9: A Study to Test How Well Different Doses of BI 764532 Are Tolerated by People With Small Cell Lung Cancer When Taken Together With a Single Agent Chemotherapy

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Male or female participants ≥18 years old and at least at the legal age of consent in countries where it is greater than 18 years at the time of signature of the informed consent form (ICF). 2. Signed and dated written informed consent in accordance with International Conference of Harmonization-Good Clinical Practice (ICH-GCP) and local legislation prior to admission to the trial. 3. Histologically or cytologically confirmed small cell lung cancer (SCLC). Patients with tumours with mixed histology are eligible only if SCLC component is predominant and represent at least 50% of the overall tumour tissue. 4. Extensive stage

•small cell lung cancer (ES-SCLC) that progressed or recurred following platinum-based treatment, and anti- programmed cell death protein 1 (PD-1) or programmed cell death ligand 1 (PD-L1) as applicable. 5. Patients must be eligible for single agent chemotherapy treatment (used in the trial) according to label. 6. Availability of archival tumour tissue sample. 7. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. Further inclusion criteria apply.

Exclusion Criteria:

1. Previous treatment in this trial. 2. Current enrolment in another investigational device or drug trial, or \<30 days since ending another investigational device or drug trial(s). 3. Untreated or symptomatic brain metastases. Participants with treated, stable brain metastases are eligible provided they meet the following criteria: * Radiotherapy or major surgery for brain metastases was completed at least 2 weeks (for radiotherapy) or 4 weeks (for major brain metastases surgery) prior to the first administration of BI 764532. * Patient is off steroids for at least 7 days (physiologic doses of steroids are permitted), and the patient is off anti-epileptic drugs for at least 7 days or on stable doses of anti-epileptic drugs for malignant central nervous system (CNS) disease. 4. Presence of leptomeningeal carcinomatosis. 5. Prior participation in clinical trials of BI 764532, including receiving standard of care in these trials OR prior treatment with T cell engager (TcE) or cell therapies targeting delta-like ligand 3 (DLL3). 6. Persistent toxicity from previous treatments that has not resolved to ≤ Common Terminology Criteria for Adverse Events (CTCAE) Grade 1 (except for alopecia, asthenia/fatigue, CTCAE Grade 2 neuropathy, or Grade 2 endocrinopathies controlled by replacement therapy). 7. Major surgery (major according to the investigator's assessment) within 28 days prior to first administration of BI 764532 or planned during treatment period, e.g. hip replacement. 8. Previous or concomitant malignancies other than the one treated in this trial within the last 2 years except 1. effectively treated non-melanoma skin cancers 2. effectively treated carcinoma in situ of the cervix 3. effectively treated ductal carcinoma in situ 4. other effectively treated malignancy that is considered cured by local treatment Further exclusion criteria apply.

Conditions & Interventions

Interventions:
DRUG: BI 764532, DRUG: Topotecan, DRUG: Single agent chemotherapy
Conditions:
Small Cell Lung Carcinoma (SCLC)

More Information

Contact(s): Boehringer Ingelheim - clintriage.rdg@boehringer-ingelheim.com
Principal Investigator:
Phase: PHASE1
IRB
Number:
System ID: NCT05990738

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