DAREON™-5: A Study to Test Whether Different Doses of BI 764532 Help People With Small Cell Lung Cancer or Other Neuroendocrine Cancers

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 Council for Harmonisation-Good Clinical Practice (ICH-GCP) and local legislation prior to admission to the trial. 3. Part 1: Histologically or cytologically confirmed, cancer of the following histologies: * Small cell lung cancer (SCLC) * Extra-pulmonary neuroendocrine carcinoma (epNEC) (except Merkel cell carcinoma (MCC), Medullary thyroid cancer (MTC) and Neuroendocrine prostate cancer (NEPC)) * Large cell neuroendocrine carcinoma (LCNEC) of the lung Patients with tumours with mixed histologies for any above type are eligible only if the neuroendocrine carcinoma/small tumour cells component is predominant and represents at least 50% of the overall tumour tissue. Patients must have progressed or recurred after standard of care therapy * SCLC: after at least two prior lines of therapy, including at least one platinum-based regimen; in countries where standard of care in first line therapy includes PD-L1 inhibitor treatment patients should have received the combination of platinum-based regimen plus PD-L1 inhibitor unless they have been unable to receive checkpoint inhibitor treatment. * Therapy includes PD-L1 inhibitor treatment; patients should have received the combination of platinum-based regimen plus PD-L1 inhibitor unless they have been unable to receive checkpoint inhibitor treatment. * epNEC/LCNEC: after at least one platinum-based regimen. Part 2: Histologically or cytologically confirmed epNEC (except MCC, MTC and NEPC) with centrally assessed DLL3 high expression status. Patients must have progressed or recurred after at least one platinum-based regimen. 4. Eastern Cooperative Oncology Group (ECOG) score of 0 or 1. 5. Measurable lesions as defined per Response Evaluation Criteria In Solid Tumours (RECIST) v 1.1 within 21 days prior to the first dose of BI 764532. 6. Part 1: Availability of archival tumour tissue sample Part 2: Availability of archival formalin-fixed paraffin-embedded (FFPE) tumour tissue sample. Following specimens are not allowed: Fine Needle Aspiration (FNA), Cytology samples, decalcified bone samples. 7. Adequate organ function as defined in the protocol. 8. All toxicities related to previous anti-cancer therapies have resolved = Common Terminology Criteria for Adverse Events (CTCAE) Grade 1 prior to trial treatment administration (except for alopecia, peripheral neuropathy, fatigue and endocrinopathies controlled by replacement therapy which must be = CTCAE Grade 2 and amenorrhea/menstrual disorders which can be any grade). 9. Women of childbearing potential (WOCBP) and men able to father a child must be ready and able to use acceptable methods of birth control per ICH M3 (R2) that result in a low failure rate of less than 1% per year when used consistently and correctly. A list of contraception methods meeting these criteria and instructions on the duration of their use is provided in the participant information Exclusion criteria: 1. Untreated or symptomatic brain metastases. (Part 2: with mandatory assessment by brain MRI within 21 days before first trial drug administration.) Participants with treated, stable brain metastases are eligible provided they meet the following criteria: * Radiotherapy or surgery for brain metastases was completed at least 2 weeks 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. 2. Presence of leptomeningeal disease or, part 2: epidural disease including spinal cord compression. 3. Part 1: Active/previous history of interstitial lung disease or non-infectious pneumonitis (any grade). Part 2: Active/previous history of interstitial lung disease, pulmonary fibrosis, organizing pneumonia or non-infectious pneumonitis (any grade). Patients with a history of therapy-related pneumonitis that is considered clinically resolved are eligible. 4. Participants who experienced severe, life-threatening immune-mediated adverse events or infusion-related reactions including those that lead to permanent discontinuation while on treatment with immuno-oncology agents. 5. Prior anti-cancer therapy: * Patients who have been treated with any other anti-cancer drug within 4 weeks or within 5 half-life periods (whichever is shorter) prior to first administration of BI 764532. * Patients who have been treated with extensive field radiotherapy including whole brain irradiation within 2 weeks prior to first administration of BI 764532. 6. Previous treatment with Delta-like ligand 3 (DLL3)-targeting T cell engagers or cell therapies. 7. Diagnosis of immunodeficiency or systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of BI 764532. Physiological replacement of steroids is allowed. 8. Unresolved toxicity from prior anti-tumour therapy, defined as per protocol. Further exclusion criteria apply.

Conditions & Interventions

Interventions:

DRUG: BI 764532, dose 1, DRUG: BI 764532, dose 2

Conditions:

Small Cell Lung Carcinoma, Neuroendocrine Neoplasms, Extra-pulmonary Neuroendocrine Carcinoma

More Information

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Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT05882058

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