# The AIRTIVITY® Study: A Study to Find Out Whether BI 1291583 Helps People With Bronchiectasis

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years and over

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

Inclusion criteria: * Male or female participants. Woman of childbearing potential (WOCBP) must be ready and able to use highly effective methods of birth control per International Council of Harmonisation (ICH) M3 (R2) that result in a low failure rate of less than 1 % per year when used consistently and correctly, as well as one barrier method. A list of contraception methods meeting these criteria is provided in the participant information. * Signed and dated written informed consent prior to admission to the study, in accordance with Good Clinical Practice (GCP) and local legislation. * Age of participants when signing the informed consent ≥18 (at least the legal age of consent in countries where it is greater than 18 years) years. * Clinical history consistent with bronchiectasis (e.g. cough, chronic sputum production, recurrent respiratory infections) and investigator confirmed diagnosis of bronchiectasis by Computed Tomography (CT) scan. Participants whose past CT scan image records are not available will undergo a chest CT scan during Screening. Historical scans must not be older than five years. * Participants should be able to produce sputum for screening. * History of documented pulmonary exacerbations requiring antibiotic treatment. In the 12 months before Visit 1, participants must have had either: * at least 2 exacerbations, or * at least 1 exacerbation and an St. George's Respiratory Questionnaire (SGRQ) Symptoms score of \>40 at screening Visit 1 For participants on stable oral or inhaled antibiotics as chronic treatment for bronchiectasis and participants on Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapy (CFTR-MT), at least one exacerbation must have occurred since initiation of stable antibiotics or CFTR-MT. Exclusion criteria: * Any new or newly diagnosed condition of primary or secondary immunodeficiency within 1 year before randomisation. * Allergic bronchopulmonary aspergillosis being treated or requiring treatment. * Tuberculosis or non-tuberculosis mycobacterial infection being treated or requiring treatment * Any findings in the medical examination and/or laboratory value assessed at Screening Visit 1 or during screening period, that in the opinion of the investigator may put the participant at risk by participating in the trial. * Any clinically relevant (at the discretion of the investigator) acute respiratory infection or ongoing pulmonary exacerbation at screening visit or during the screening unless recovered in the opinion of the investigator prior to Visit 2. * Any relevant pulmonary, gastrointestinal, hepatic, renal, cardiovascular, metabolic, immunological, hormonal, or other disorder that, in the opinion of the investigator, may put the participant at risk by participating in the study. * Major surgery (major according to the investigator's assessment) performed within 6 weeks prior to randomisation or scheduled during trial period. * Any documented active or suspected malignancy or history of malignancy within 5 years prior to screening, except appropriately treated in situ non-melanoma skin cancers or in situ carcinoma of uterine cervix. * Evidence or medical history of moderate or severe liver disease (Child-Pugh score B or C hepatic impairment). * estimated Glomerular Filtration Rate (eGFR) according to Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula \<30 mL/min at Visit 1. * Previous treatment with a dipeptidyl peptidase-1 (DPP1) (Cathepsin C (CatC)) inhibitor. (Note: Participants that were randomised and only received placebo in studies with DPP1 (CatC) inhibitor are allowed.) Further exclusion criteria apply.

## Conditions & Interventions

**Interventions:**

DRUG: BI 1291583, DRUG: Placebo matching BI 1291583

**Conditions:**

Bronchiectasis

## More Information

**Contact(s):** Boehringer Ingelheim - clintriage.rdg@boehringer-ingelheim.com

**Principal Investigator:**

**Phase:** PHASE3

**IRB**

**Number:**

**System ID:** NCT06872892